As confidentially submitted with the Securities and Exchange Commission on April 27, 2021. This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Rallybio Holdings, LLC

(to be succeeded by Rallybio Corporation in the reorganization)
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**82-4956058**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

234 Church Street, Suite 1020
New Haven, CT 06510
(203) 859-3820
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Martin W. Mackay, Ph.D.
Chief Executive Officer
234 Church Street, Suite 1020
New Haven, CT 06510
(203) 859-3820
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Marc Rubenstein **Zachary Blume** **Ropes & Gray LLP** **Prudential Tower** **800 Boylston Street** **Boston, MA 02199-3600** **(617) 951-7000**	**Michael Greco** **General Counsel** **234 Church Street, Suite 1020** **New Haven, CT 06510** **(203) 859-3820**	**Lisa Firenze** **Molly W. Fox** **Wilmer Cutler Pickering Hale & Dorr LLP** **7 World Trade Center** **250 Greenwich Street** **New York, NY 10007** **(212) 230-8880**

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (1)	AMOUNT OF REGISTRATION FEE (2)
Common Stock, par value $ per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

We currently operate as Rallybio Holdings, LLC, a Delaware limited liability company, or the LLC Entity. Prior to the completion of this offering, we intend to complete a series of transactions pursuant to which (i) Rallybio IPD, LLC, a direct subsidiary of the LLC Entity, will be converted from a Delaware limited liability company to a Delaware corporation and change its name to Rallybio Corporation, or the Corporation, (ii) the Corporation will form four direct subsidiaries, each a Delaware limited liability company, or collectively the Merger Subs, (iii) each of the Merger Subs will consummate a separate merger with one of the LLC Entity's direct subsidiaries, other than Rallybio IPD, LLC, or collectively the Asset Subsidiaries, with the Asset Subsidiaries surviving the mergers and the LLC Entity receiving common stock of the Corporation in exchange for its interest in each Asset Subsidiary, which will result in the Asset Subsidiaries becoming subsidiaries of the Corporation and the Corporation becoming the only direct subsidiary of the LLC Entity, and (iv) following this series of mergers, the LLC Entity will liquidate and distribute 100% of the capital stock of the Corporation, consisting solely of common stock, to the unitholders of the LLC Entity. We refer to these transactions throughout the prospectus included in this registration statement collectively as the "Reorganization." As a result of the Reorganization, the unitholders of the LLC Entity will become the holders of common stock of the Corporation, and the Corporation will become the registrant for purposes of this offering, and our combined and consolidated financial statements will be reported from the Corporation. See "The Reorganization" for further detail regarding these transactions.

Shares of the common stock of the Corporation are being offered by the prospectus included in this registration statement.

FINANCIAL STATEMENT PRESENTATION

Except as disclosed in this prospectus, the audited consolidated financial statements for the years ended December 31, 2020 and 2019 and the notes thereto, and selected historical consolidated financial data and other financial information included in this registration statement are those of the LLC Entity and do not give effect to the Reorganization.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED , 2021

PRELIMINARY PROSPECTUS

Shares

Rallybio Holdings, LLC

Common Stock

We are offering shares of our common stock. This is an initial public offering, and no public market currently exists for our common stock. We expect the initial public offering price to be between $ and $ per share. We intend to apply for listing of our common stock on the Nasdaq Global Market under the symbol " ."

We are an "emerging growth company" and a "smaller reporting company" under federal securities laws and are subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

	PER SHARE	TOTAL
Initial public offering price	$	$
Underwriting discounts and commissions (1)	$	$
Proceeds to us, before expenses	$	$

(1) See "Underwriting" for additional disclosure regarding underwriting compensation.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock is expected to be made on or about , 2021. We have granted the underwriters an option for a period of 30 days to purchase an additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Jefferies **Cowen** **Evercore ISI**

Prospectus dated , 2021.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

TRADEMARKS

We use Rallybio as a trademark in the United States and/or in other countries. This prospectus contains references to our trademark and to those belonging to other entities, including Affibody®. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research and studies conducted by third parties. We believe that the information from these third-party publications, research and studies included in this prospectus is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

REORGANIZATION

Prior to the completion of this offering, we intend to complete a series of transactions pursuant to which (i) Rallybio IPD, LLC, a direct subsidiary of the LLC Entity, will be converted from a Delaware limited liability company to a Delaware corporation and change its name to Rallybio Corporation, or the Corporation, (ii) the Corporation will form four direct subsidiaries, each a Delaware limited liability company, or collectively the Merger Subs, (iii) each of the Merger Subs will consummate a separate merger with one of the LLC Entity's direct subsidiaries, other than Rallybio IPD, LLC, or collectively the Asset Subsidiaries, with the Asset Subsidiaries surviving the mergers and the LLC Entity receiving common stock of the Corporation in exchange for its interest in each Asset Subsidiary, which will result in the Asset Subsidiaries becoming subsidiaries of the Corporation and the Corporation becoming the only direct subsidiary of the LLC Entity, and (iv) following this series of mergers, the LLC Entity will liquidate and distribute 100% of the capital stock of the Corporation, consisting solely of common stock, to the unitholders of the LLC Entity. We refer to these transactions throughout the prospectus included in this registration statement collectively as the "Reorganization." As a result of the Reorganization, the unitholders of the LLC Entity will become the holders of common stock of the Corporation, and the Corporation will become the registrant for purposes of this offering, and our combined and consolidated financial statements will be reported from the Corporation. See "The Reorganization" for further detail regarding these transactions.

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PROSPECTUS SUMMARY

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in the prospectus, before making any investment decision. Except where the context otherwise requires or where otherwise indicated, the terms "Rallybio," "we," "us," "our," "our company," "the company," and "our business" refer, prior to the Reorganization discussed below, to Rallybio Holdings, LLC and its consolidated subsidiaries and, after the Reorganization, to Rallybio Corporation and its consolidated subsidiaries.

Overview

We are a clinical-stage biotechnology company built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing and delivering therapies that meaningfully improve the lives of patients suffering from severe and rare diseases. Our mission at Rallybio is aligned with our expertise, and we believe we have assembled the best people, partners and science to forge new paths to life-changing therapies. Since our launch in January 2018, we have acquired a portfolio of promising product candidates that consists of five programs, and we are focused on further expanding our portfolio with the goal of making a profound impact on the lives of even more patients. We are drawing on our decades of knowledge and experience with a determination to tackle the undone, the too difficult, the inaccessible – and change the odds for rare disease patients.

Our most advanced program is for the prevention of fetal and neonatal alloimmune thrombocytopenia, or FNAIT, a potentially life-threatening rare hematological disease that impacts fetuses and newborns. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. We plan to move this program forward with our lead product candidate, RLYB212, a monoclonal anti-HPA-1a antibody, and submit an Investigational New Drug application, or IND, for RLYB212 in . We are also focused on developing therapies that address diseases of complement dysregulation, including paroxysmal nocturnal hemoglobinuria, or PNH, generalized myasthenia gravis, or gMG, and ophthalmic disorders. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with PNH and gMG. We expect to submit a clinical trial application, or CTA, for RLYB116 in . RLYB114 is a pegylated C5 inhibitor in preclinical development for the treatment of complement-mediated ophthalmic diseases, and we expect to submit a CTA for this product candidate in . Additionally, in collaboration with Exscientia Limited, or Exscientia, we have two discovery-stage programs focused on the identification of small molecule therapeutics for patients with rare metabolic diseases.

Our Approach

At Rallybio, we do not accept that millions of patients suffering from devastating rare diseases should have to live without transformative treatments. There are an estimated 25 to 30 million people affected by as many as 7,000 rare diseases in the United States alone, with a significantly greater number of affected people globally. We are building a diversified pipeline of product candidates that we believe have the potential to transform the lives of patients in need. Our goal is to deliver therapeutics that provide meaningful clinical benefits to patients so they can become unbound and undefined by the diseases from which they suffer.

We believe the success of our company is built on three key strengths:

- **Our extensive knowledge of rare diseases and our scientific expertise positions us to identify therapies with the potential for transformative impact.** We seek to acquire and develop product candidates that possess a clear mechanism of action and that aim to address diseases with a well-understood pathophysiology for which there is a significant unmet medical need. We believe that a product candidate's mechanism of action should target the causal biology of the disease to provide the highest

probability of dramatically improving the lives of patients. We believe that our team's extensive experience in rare diseases and our scientific expertise position us to identify opportunities where these links can be made, which may go unnoticed by others.

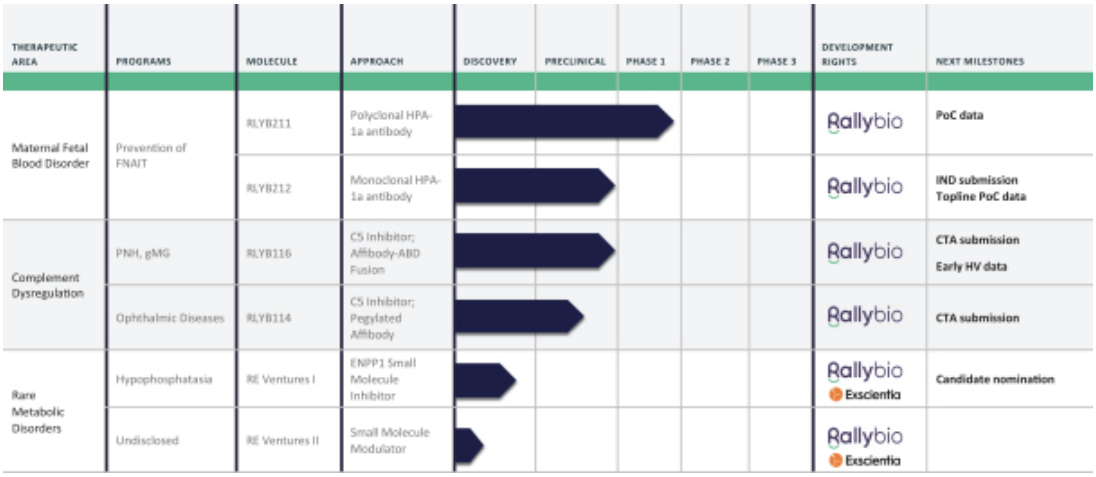
- **Our ability to source, to identify and to evaluate potential high-quality product candidates**. We apply decades of experience across drug discovery, research, development, regulatory strategy and manufacturing to source, to identify and to evaluate therapeutic targets and product candidates that we believe have a high probability of success. Our ability to source these product candidates is facilitated by our extensive network of relationships with leaders in industry and in academic clinical centers worldwide. We view ourselves as partners of choice given our team's track record of success in developing and delivering new therapies to patients.
- **Our team's proven execution capability to drive product candidates through clinical development to regulatory approvals.** We have assembled a team with a proven history of successfully advancing product candidates from discovery to clinical development and through regulatory approval. Members of our team have played critical roles in the approval of more than 30 drugs and secured approvals from regulatory authorities in the Americas, Europe, Australia, and Asia. In doing so, our employees previously developed and implemented novel clinical trial designs and successfully conducted clinical trials in never-before treated patient populations. We believe this collective prior experience positions us to efficiently and expertly execute at each step in the research and development process and enhances the value we can bring to product candidates and to patients.

Our Company

We were founded in January 2018 by Martin W. Mackay, Ph.D., Stephen Uden, M.D., and Jeffrey M. Fryer, CPA to identify and accelerate the development of life-transforming therapies for patients with severe and rare disorders. Our founders were previously executives at Alexion Pharmaceuticals, Inc., where Dr. Mackay was Global Head of Research & Development, Dr. Uden served as Head of Research, and Mr. Fryer was Chief Tax Officer. We believe our team's prior industry contributions have made a significant positive impact on the lives of thousands of patients around the world. As a strong and experienced team, we believe we can transform the lives of thousands more.

Our Pipeline

Our pipeline is illustrated in the chart below.



FNAIT: Fetal and neonatal alloimmune thrombocytopenia; HPA-1a: Human platelet antigen 1a; PNH: Paroxysmal nocturnal hemoglobinuria; gMG: Generalized myasthenia gravis; ABD: Albumin-binding domain; ENPP1: Ectonucleotide pyrophosphatase/phosphodiesterase 1; PoC: Proof of concept; IND: Investigational new drug; CTA: Clinical trial application; HV: Healthy volunteer

RLYB211 and RLYB212 for the Prevention of FNAIT

FNAIT is a potentially life-threatening rare disease that can cause uncontrolled bleeding in fetuses and newborns. FNAIT can arise during pregnancy due to an immune incompatibility between an expectant mother and her fetus in a specific platelet antigen called human platelet antigen 1, or HPA-1. We estimate that there are over 22,000 pregnancies at high risk of developing FNAIT each year in the United States, Canada, United Kingdom, other major European countries and Australia. There is currently no approved therapy for the prevention or treatment of FNAIT.

The lead product candidate in our FNAIT prevention program is RLYB212, a preclinical-stage monoclonal anti-HPA-1a antibody. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. Data generated from the first cohort of healthy participants in this trial demonstrated the ability of an anti-HPA-1a antibody to rapidly eliminate transfused HPA-1a positive platelets from the circulation of healthy HPA-1a negative participants. Based on these results, we believe that targeting HPA-1a with an anti-HPA-1a antibody has the potential to prevent maternal alloimmunization and therefore the occurrence of FNAIT.

We expect to submit an IND for RLYB212 in , and to initiate a Phase 1 clinical trial in healthy participants by . We anticipate reporting additional data from our Phase 1/2 clinical trial for RLYB211 in .

RLYB116 and RLYB114 for the Treatment of Diseases Related to Complement Pathway Dysregulation

Our next two programs target diseases related to complement pathway dysregulation. The complement system plays a central role in innate immunity, as well as shaping adaptive immune response. Dysregulation of the complement pathway has been implicated in the pathogenesis of a growing number of diseases, making it an attractive target for therapeutic intervention. Antibody inhibitors of C5 have been successfully developed to treat diseases caused by complement pathway dysregulation, including PNH, refractory gMG, atypical hemolytic uremic syndrome, and relapsing neuromyelitis optica spectrum disorder. Despite the approval of antibody-based C5 inhibitors for patients with these diseases, we believe there remains significant need in the market for safe, effective, patient-friendly and accessible therapies.

Our team has a track record of success and significant expertise in designing, developing and securing approval for complement inhibitors, including Soliris and Ultomiris, for patients with severe and rare diseases around the world. We believe our internal knowledge and expertise positions us to successfully advance our programs and deliver transformative benefits to patients in need.

Our most advanced product candidate in this therapeutic area is RLYB116, an inhibitor of complement factor C5, which is a central component of the complement pathway. RLYB116 is an Affibody® **molecule attached to an albumin binding domain that has the potential to drive the rapid, complete and sustained inhibition of C5 with a subcutaneous injection. We plan to pursue PNH and gMG as our lead indications for RLYB116. We also plan to evaluate the development of RLYB116 for the treatment of additional rare complement-mediated diseases. We expect to submit a CTA for RLYB116 in , and to initiate a Phase 1 clinical trial by .**

Our second C5 inhibitor, RLYB114, is a pegylated C5-targeted Affibody® molecule with pharmacokinetic properties designed for the treatment of complement-mediated ophthalmic diseases. Preclinical data generated with RLYB114 demonstrate that it is well-tolerated in animal models with no serious adverse effects. We expect to submit a CTA for RLYB114 in .

Artificial Intelligence Drug Discovery Collaboration with Exscientia

We have established a partnership with Exscientia, an Oxford, UK-based artificial intelligence-driven pharmatech company that is a leader in the use of computational tools and machine learning capabilities to rapidly and efficiently discover novel small molecule drug candidates. Our partnership consists of two joint ventures that each focus on the discovery and development of small molecule therapeutics for the treatment of patients with rare metabolic diseases.

Our Strategy

Our mission at Rallybio is aligned with our expertise: to identify and accelerate the development of life-transforming therapies for patients with severe and rare disorders. To achieve this mission, our strategy includes the following key components:

- Establish a leading rare disease company through a team that delivers transformative medicines to patients;
- Rapidly advance RLYB212 through clinical development for the prevention of FNAIT;
- Rapidly advance RLYB116 and RLYB114 through clinical development for the treatment of diseases of complement dysregulation;
- Identify and advance pipeline product candidates for rare metabolic diseases through our joint ventures with Exscientia;
- Expand our pipeline through partnering, acquiring or in-licensing additional product candidates that target validated biology; and
- Maximize the value of pipeline product candidates through commercial independence in key markets and select partnerships.

Summary of Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability;
- Even if this offering is successful, we will require significant additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of RLYB212, RLYB116 or any additional product candidates we may develop;
- Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- The ongoing COVID-19 pandemic in the United States and other countries has resulted in and may further result in disruptions to our preclinical studies, clinical trials, manufacturing and other business operations, which could adversely affect our business and the market price of our common stock;
- We are heavily dependent on the success of RLYB212 and RLYB116, which are in preclinical IND-enabling activities. If we are not able to develop, obtain regulatory approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed;
- We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business;
- Preclinical studies and clinical trials are expensive, time consuming, and difficult to design and implement, and involve uncertain outcomes. Any product candidates that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including our focus on rare diseases;

- Results of preclinical studies, clinical trials, or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results;
- Any product candidates that we develop or the administration thereof, may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales;
- The regulatory approval processes of the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and comparable foreign regulatory authorities are lengthy, time- consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for RLYB212, RLYB116 or any of our other product candidates, our business will be substantially harmed;
- Our product candidates target rare diseases and conditions, and the market opportunities for RLYB212 and RLYB116, if approved, may be smaller than we anticipate. As a result, our commercial opportunity may be limited and because the target populations of our product candidates are for rare diseases, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth;
- The FDA, EMA or other comparable foreign regulatory authorities could require the clearance or approval of an in vitro diagnostic or companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy and we may not realize the commercial potential of any such product candidate;
- We face significant competition from biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively;
- We intend to continue to acquire or in-license rights to additional product candidates or collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources; and
- If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see “Risk Factors.”

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.07 billion in annual revenue, we have more than

$700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one Annual Report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We may continue to be a smaller reporting company until the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

Our Corporate Information

Rallybio Holdings, LLC, or the LLC Entity, was formed in Delaware in March 2018. Rallybio IPD, LLC was formed in Delaware in May 2020. Prior to the completion of this offering, Rallybio IPD, LLC will be converted into a Delaware corporation and change its name to Rallybio Corporation, or the Corporation. The Corporation will be the issuer of the shares of common stock being offered by this prospectus. See “The Reorganization.” Our principal executive offices are located at 234 Church Street, Suite 1020, New Haven, CT 06510 and our telephone number is (203) 859-3820. Our corporate website address is https://www.rallybio.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Reorganization

Prior to the completion of this offering, we intend to complete a series of transactions pursuant to which (i) Rallybio IPD, LLC, a direct subsidiary of the LLC Entity, will be converted from a Delaware limited liability company to a Delaware corporation and change its name to Rallybio Corporation, (ii) the Corporation will form four direct subsidiaries, each a Delaware limited liability company, or collectively the Merger Subs, (iii) each of the Merger Subs will consummate a separate merger with one of the LLC Entity's direct subsidiaries, other than Rallybio IPD, LLC, or collectively the Asset Subsidiaries, with the Asset Subsidiaries surviving the mergers and the LLC Entity receiving common stock of the Corporation in exchange for its interest in each Asset Subsidiary, which will result in the Asset Subsidiaries becoming subsidiaries of the Corporation and the Corporation becoming the only direct subsidiary of the LLC Entity, and (iv) following this series of mergers, the LLC Entity will liquidate and distribute 100% of the capital stock of the Corporation, consisting solely of common stock, to the unitholders of the LLC Entity. See "The Reorganization" and "Description of Capital Stock" for additional information, including a description of the terms of our capital stock following the Reorganization and the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect prior to the consummation of this offering.

The number of shares of common stock that holders of incentive units will receive in the Reorganization will be based on the fair value per common unit, as determined by our board of managers, immediately prior to the Reorganization. In this prospectus, we have assumed a fair value of $ per common unit, which is the midpoint of the price range per share set forth on the cover page of this prospectus. Based on an assumed fair value of $ per common unit, the incentive units will convert into an aggregate of shares of our common stock. At a fair value of $ per common unit, which is the high end of the price range per share set forth on the cover page of this prospectus, the incentive units would convert into an aggregate of shares of our common stock. At a fair value of $ per common unit, which is the low end of the price range set forth on the cover page of this prospectus, the incentive units would convert into an aggregate of shares of our common stock.

As a result of the Reorganization, based on an assumed fair value of $ per common unit, which is the midpoint of the price range per share set forth on the cover page of this prospectus, the holders of existing units in the LLC Entity will collectively own an aggregate of shares of common stock of the Corporation as of immediately prior to the consummation of this offering. See "The Reorganization."

THE OFFERING

Common stock offered by us	shares.
Common stock to be outstanding after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares of common stock from us	We have granted the underwriters an option to purchase up to an aggregate of additional shares of common stock from us at the initial public offering price, less the estimated underwriting discounts and commissions, for a period of 30 days after the date of this prospectus.
Use of proceeds	We estimate that our net proceeds from the sale of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with cash on hand, as follows: (i) to advance our FNAIT prevention program, including completion of our Phase 1/2 clinical trial for RLYB211 and completion of our Phase 1 and Phase 1b clinical trials for RLYB212, (ii) to advance our complement program, including completion of our Phase 1a clinical trial and initiation of our Phase 1b clinical trial for RLYB116, and initiation of our Phase 1 clinical trial for RLYB114, (iii) to advance our joint ventures with Exscientia, including the initiation of our Phase 1 clinical trial for our ENPP1 inhibitor, and (iv) any remaining proceeds for business development activities and other general corporate purposes. See "Use of Proceeds."
Dividend policy	We do not anticipate declaring or paying any cash dividends on our capital stock in the foreseeable future. See "Dividend Policy."
Risk factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	" "

The number of shares of our common stock to be outstanding immediately following the completion of this offering is based on shares outstanding as of March 31, 2021, after giving effect to the Reorganization, including the issuance by the Corporation of an aggregate of shares of its common stock and the subsequent distribution of those shares to members of the LLC Entity, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. These amounts exclude:

- shares of our common stock reserved for issuance under the Rallybio Corporation 2021 Equity Incentive Plan, or the 2021 Plan, which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under the Rallybio Corporation 2021 Employee Stock Purchase Plan, or the ESPP, which will become effective in connection with this offering.

Except as otherwise noted, all information in this prospectus assumes or gives effect to:

- the completion of the Reorganization, including the distribution to the members of the LLC Entity of all outstanding units of the Corporation as of , 2021 for an aggregate of shares of common stock of the Corporation, prior to the completion of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock from us;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws prior to the consummation of this offering; and
- no issuance of stock options on or after , 2021, under the Rallybio Holdings, LLC 2018 Share Plan, or the 2018 Plan, or the 2021 Plan.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this prospectus and our financial statements and the related notes included elsewhere in this prospectus. The statements of operations and comprehensive loss data for the years ended December 31, 2020 and 2019 and the balance sheet data as of December 31, 2020 and 2019 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations and comprehensive loss data for the three months ended March 31, 2021 and 2020 and our balance sheet as of March 31, 2021 have been derived from our unaudited financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands, except share and per share amounts)	YEAR ENDED DECEMBER 31, 2020	2019	THREE MONTHS ENDED MARCH 31, 2021	2020
Statement of Operations and Comprehensive Loss Data:				
Operating expenses:				
Research and development	$ 17,630	$ 11,366		
General and administrative	7,673	6,276		
Total operating expenses	25,303	17,642		
Loss from operations	(25,303)	(17,642)		
Other income (expense):				
Interest income	171	197		
Interest expense	(49)	(39)		
Other income	241	167		
Change in fair value of Series A-2 financing right obligation	—	(143)		
Total other income, net	363	182		
Loss before income taxes	(24,940)	(17,460)		
Income tax benefit	(15)	—		
Loss on investment in joint venture	1,522	103		
Net loss and comprehensive loss	$ (26,447)	$ (17,563)		
Net loss per common unit, basic and diluted (1)	$ (9.95)	$ (10.24)		
Weighted average common units outstanding, basic and diluted (1)	2,659,187	1,715,164		
Pro forma net loss per share, basic and diluted (1)	$			
Pro forma weighted average common stock outstanding, basic and diluted (1)				

(in thousands)	MARCH 31, 2021 ACTUAL	PRO FORMA (3)	PRO FORMA AS ADJUSTED (4)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$	$	
Working capital (2)			
Total assets			
Total liabilities			
Redeemable Convertible Preferred Units			
Accumulated deficit			
Total members' (deficit), actual; total unitholders' equity, pro forma and pro forma as adjusted	$	$	

(1) See Note 11 to our financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common unitholders.

(2) We define working capital as current assets, less current liabilities.

(3) The pro forma balance sheet data gives effect to (i) the Reorganization, including the issuance by the Corporation of an aggregate of shares of its common stock and the subsequent distribution of those shares to members of the LLC Entity, prior to the completion of this offering, as if the Reorganization had occurred as of March 31, 2021, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws.

(4) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total unitholders' equity (deficit) by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total unitholders' equity by approximately $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and related notes appearing at the end of this prospectus and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our common stock. Some of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic (including any resurgences thereof) and any worsening of the global business and economic environment as a result. Negative consequences from these risks could harm our business, prospects, operating results and financial condition or cause the trading price of our common stock to decline, which could result in the loss of all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See "Special Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a limited operating history. As a result, we are not profitable and have incurred significant losses since our formation. We had net losses of $26.4 million and $17.6 million for the years ended December 31, 2020 and 2019, respectively, and net losses of $ million and $ million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $ million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our five programs and our Phase 1/2 clinical trial for RLYB211. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

We expect to incur significant additional operating losses in the foreseeable future as we advance our programs through preclinical and clinical development, expand our research and development activities, acquire and develop new product candidates, complete preclinical studies and clinical trials, finance our business development strategy, seek regulatory approval for the commercialization of our product candidates and commercialize our products, if approved. The costs of advancing product candidates through each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any product candidate to marketing approval in even a single jurisdiction are substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will increase substantially if and as we:

- file an Investigational New Drug application, or IND, and initiate a Phase 1 clinical trial for RLYB212, our lead product candidate for our fetal and neonatal alloimmune thrombocytopenia, or FNAIT, program;
- file an IND or a clinical trial application, or CTA, and initiate our clinical trials for RLYB116 and other product candidates;
- initiate a natural history alloimmunization study of FNAIT, or our FNAIT Natural History Alloimmunization Study, to support our development program and related regulatory submissions for RLYB212;
- continue to develop and conduct clinical trials with respect to RLYB211;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;

- continue and expand upon our discovery and development joint ventures with Exscientia Limited, or Exscientia;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- add operational, financial, and management personnel, including personnel to support our product development and planned future commercialization efforts and to support our transition to a public company;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any product candidate for which we obtain regulatory approval; and
- establish a sales, marketing, and distribution infrastructure to commercialize our programs, if approved, and for any other product candidates for which we may obtain marketing approval.

We do not know when or whether we will become profitable. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates and to obtain the necessary regulatory approvals for their commercialization, which is subject to substantial additional risks and uncertainties, as described under "— Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval." Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur net losses and negative cash flows in the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through current or future collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we successfully commercialize RLYB212, RLYB116 or any of our other product candidates, we may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis or meet outside expectations for our profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, execute our business plan or continue our operations.

Even if this offering is successful, we will require significant additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of RLYB212, RLYB116 or any additional product candidates we may develop.

We expect to spend significant amounts of capital to complete the development of, seek regulatory approvals for and, if approved, commercialize RLYB212 and RLYB116. These expenditures will include costs related to our ongoing Phase 1/2 clinical trial for RLYB211. We expect similar expenditures as we initiate our planned clinical trials for RLYB212 and for RLYB116, and our FNAIT Natural History Alloimmunization Study. In addition, we are obligated to make certain milestone and royalty payments in connection with achievement of certain development and commercial milestones as well as the sale of resulting products under our agreements with Prophylix AS, or Prophylix, Swedish Orphan Biovitrum AB (Publ), or Sobi, and Affibody AB, or Affibody. We may also spend significant capital to develop laboratory tests, and if required by the U.S. Food and Drug Administration, or the FDA, or other healthcare agencies, one or more companion diagnostics, to identify patients for inclusion in our clinical trials or who are likely to respond to our product candidates.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements for more than from the date of this prospectus. This estimate and our expectation regarding the sufficiency of the net proceeds from this offering to advance the preclinical and clinical development of RLYB212,

RLYB116 and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate. Changing circumstances, including any unanticipated expenses, could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because of the numerous risks and uncertainties, the length of time and scope of activities associated with development of RLYB212, RLYB116 or any product candidate we may develop is highly uncertain, we are unable to estimate the actual amount of funds we will require for development, approval and any approved marketing and commercialization activities. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including our ongoing Phase 1/2 clinical trial for RLYB211, the planned clinical trials for RLYB212 and RLYB116 and the development of any other product candidates;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities, including any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for RLYB212 or any other product candidates, including design, manufacturing and regulatory approval;
- the cost of filing, prosecuting, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- our ability to develop and commercialize products that are considered medically and/or financially differentiated to competitive products by physicians, patients and payers;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of making royalty, milestone or other payments under any future in-license agreements;
- our ability to maintain our collaboration with Exscientia on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies;
- the severity, duration and impact of the COVID-19 pandemic, which may adversely impact our business;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- the initiation, progress and timing of our commercialization of RLYB212, RLYB116, if approved, or any other product candidates;
- the availability of third-party coverage and reimbursement for and pricing of any approved products; and
- the costs of operating as a public company.

Even with the net proceeds from this offering, we will require significant additional capital to advance the development and potential commercialization of our product candidates, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Depending on our business performance, the economic climate and market conditions, we may be unable to raise additional funds when needed on acceptable terms, or at all. Moreover, the COVID-19 pandemic is impacting the global economy, and the U.S. economy in particular, with the potential for the

economic downturn to be severe and prolonged. A severe or prolonged economic downturn as a result of the COVID-19 pandemic could result in a variety of challenges for our business, including disruptions in the financial markets, which could adversely impact our ability to raise additional capital when needed or on acceptable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may need to significantly delay, scale back or discontinue the development of one or more of our product candidates or the commercialization of any product that may be approved for marketing, and we could be forced to discontinue operations. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the future sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. Any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or product candidates. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We were formed in January 2018, and our operations to date have been limited to financing and staffing our company, identifying, evaluating and acquiring or in-licensing product candidates and technologies, conducting preclinical studies and our clinical trial for RLYB211 and preclinical studies for RLYB212 and RLYB116, and developing a pipeline of other preclinical and research programs. We have not yet demonstrated the ability to complete successfully a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

Our quarterly and annual financial results may fluctuate, which makes our results difficult to predict and may cause our results to fall short of expectations.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this prospectus:

- variations in the level of expense related to the ongoing development of our product candidates or research pipeline;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing and commercializing our product candidates;
- our relationships, and any associated exclusivity terms, with strategic collaborators;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements, or the termination or modification of any such existing or future arrangements;
- our operation in a net loss position in the foreseeable future;
- our ability, ourselves or with collaborators, to develop a companion diagnostic, if required, and obtain marketing approval;
- our ability to consistently manufacture our product candidates, including in sufficient quantities for clinical or commercial purposes;
- our dependence on, and the need to attract and retain, key management and other personnel;
- developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain and maintain patent protection for our product candidates;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- business interruptions such as power outages, strikes, civil unrest, wars, acts of terrorism or natural disasters;
- potential advantages that our competitors and potential competitors may have in developing and commercializing competing technologies or products, securing funding for or obtaining the rights to critical intellectual property;
- regulatory developments affecting our product candidates or those of our competitors; and
- our ability to use our net operating loss, or NOL, and income tax credit carryforwards to offset income tax.

Due to these and other factors, the results of any of our prior quarterly or annual periods should not be relied upon as indications of our future operating performance, and a period-to-period comparison of our results of operations may not be a meaningful indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Our ability to use our net operating loss and income tax credit carryforwards to offset future income tax liabilities may be subject to certain limitations.

We have incurred substantial NOLs during our history. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration. Federal NOLs generated in taxable years beginning after December 31, 2017 generally may not be carried back to prior taxable years except that, under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal NOLs generated in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the taxable year in which the loss arises. Additionally, the deduction for NOLs arising in taxable years beginning after December 31, 2017 is generally limited to 80% of current year taxable income, however, as a result of the CARES Act, for taxable years beginning before January 1, 2021, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is not so limited. We also have substantial federal and state research and development and other tax credit carryforwards that expire at various dates. These tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We may experience such ownership changes in the future as a result of this offering and/or future transactions in our stock, some of which may be outside our control. If we undergo an ownership change in connection with or after this offering, our ability to use our NOLs and income tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval

The ongoing COVID-19 pandemic in the United States and other countries has resulted in and may further result in disruptions to our preclinical studies, clinical trials, manufacturing and other business operations, which could adversely affect our business and the market price of our common stock.

The ongoing global COVID-19 pandemic is impacting worldwide economic activity, particularly economic activity in the United States, and poses the risk that we or our employees, contractors, suppliers, or other partners may be prevented from or delayed in conducting business activities for an indefinite period of time, including due to shutdowns, quarantines and other public health measures that may be requested or mandated by governmental authorities. The continued prevalence of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing or clinical trials, cause diversion of healthcare resources away from the conduct of preclinical and clinical trial matters to focus on pandemic concerns, limit travel in a manner that interrupts key trial activities, such as trial site initiations and monitoring, delay regulatory filings with regulatory agencies in affected areas or adversely affect our ability to obtain or timing to obtain regulatory approvals. These actions have in the past, continue to and could in the future negatively affect our preclinical studies, clinical trials, manufacturing and other business operations, including:

- **Preclinical studies and clinical trials:** The impact of COVID-19 may cause delays and disruptions to some of our preclinical studies and clinical trials. The response to COVID-19 by healthcare providers may delay site initiation, may slow down enrollment and make the ongoing collection of data for patients enrolled in trials more difficult or intermittent. In addition, some participants and clinical investigators may be unable or unwilling to comply with clinical trial protocols. For example, quarantines or other travel limitations have been implemented in many countries and across the United States that may impede participant movement, affect sponsor access to study sites, and/or interrupt healthcare services, which may negatively impact the execution of clinical trials. We are initiating a global natural history study for FNAIT in 2021 that requires screening a large number of potential participants, and we could experience delays in screening due to COVID-19. Significant delays or disruptions to our preclinical studies or clinical trials could adversely affect our ability to timely initiate studies, conduct successful studies, generate scientifically robust clinical data, obtain regulatory approvals or commercialize our product candidates.
- **Manufacturing and supply:** We have encountered only limited disruptions to our manufacturing and supply chain as a result of COVID-19 to date, which have not had a material adverse impact on our business, but significant or prolonged disruptions could materially impact our business, operations or financial results. Even if our manufacturing operations are not materially disrupted, pandemic-related disruptions in other businesses, such as shipping and logistics companies, could affect the availability of our product candidates for our preclinical studies and clinical trials.
- **Operations:** In accordance with direction from state and local government authorities to protect the health of our employees, their families, and our communities, we made several changes to our operations in response to COVID-19. This response included performing all office-based work outside of the office. Our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, remote working could increase our cyber security risk. Government authorities could impose further restrictions, including mandated shutdown of businesses, which may negatively affect our operations.

- **Stock Price:** The extent and duration of the impact of the COVID-19 pandemic on our stock price following this offering is uncertain. The COVID-19 pandemic may cause our stock price to be more volatile, and our ability to raise capital could be impaired.

Regulatory agencies may redirect resources in response to the COVID-19 pandemic in a way that would adversely impact our ability to progress and achieve regulatory approvals. In addition, measures intended to limit in-person interactions with regulatory agencies may interfere with our ability to hold required regulatory meetings and restrict the feedback necessary to advance filings. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are monitoring the potential impact of the COVID-19 pandemic on our business and financial statements. To date, we have not incurred impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our financial statements.

We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, including the availability and administration of vaccines, and the duration and intensity of the related effects.

We are heavily dependent on the success of RLYB212 and RLYB116, which are in preclinical IND-enabling activities. If we are not able to develop, obtain regulatory approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

Our lead programs are in early-stage clinical development or preclinical IND-enabling activities, and we do not currently have any commercial products that generate revenues or any other sources of revenue. To date, we have invested a significant portion of our efforts and financial resources in the development of RLYB211 and RLYB212 for the prevention of FNAIT and the development of RLYB116. Our future success is substantially dependent on our ability to successfully complete preclinical and clinical development for, obtain regulatory approval for, and successfully commercialize, our product candidates, which may never occur. We currently have no products that are approved for commercial sale and may never be able to develop a marketable product.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate the safety and efficacy of our investigational product candidates for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. Ongoing and future preclinical studies and clinical trials of our product candidates may not show sufficient safety or efficacy or be of sufficient quality to obtain or maintain regulatory approvals. There can be no assurance that any of our product candidates, even if approved, will prove to be commercially viable therapeutics.

RLYB212 and RLYB116 are designed for subcutaneous self-administration. The formulation or physical properties of RLYB212 and RLYB116 may ultimately be determined to be inadequate to support this route of administration. If subcutaneous administration is not feasible, then we may need to identify additional formulations or routes of administration, which could delay initiation of our clinical trials or commercialization and result in significant additional costs. Further, alternative formulations and routes of administration may be required to differentiate our product candidates from competitors and/or secure access to support successful commercialization.

Commercialization of product candidates we may develop will require additional preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA;

obtaining manufacturing supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. The success of our most advanced product candidates and other product candidates will depend on several factors, including the following:

- successful and timely initiation of preclinical studies, and successful and timely initiation of, enrollment in, and completion of our clinical trials with results that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations within the timeframes we have projected;
- regulatory grants of authorization to proceed under INDs or CTAs such that we can commence planned or future clinical trials of our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for our product candidates, and if required, in vitro diagnostic devices including companion diagnostics;
- our ability to successfully utilize certain delivery systems, such as pre-filled syringes, or PFSs, pen-injectors and/or autoinjectors, for certain of our product candidates and to obtain regulatory approval of any such drug/device combination product;
- the outcome, timing, and cost of meeting regulatory requirements, including any post-marketing commitments, established by the FDA, EMA and other comparable foreign regulatory authorities;
- establishing commercially viable arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution capabilities, whether alone or through a collaboration, to support commercialization of our product candidates, if and when approved;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively differentiating and competing with other therapies approved and/or used for the same indications as our product candidates, particularly RLYB116;
- establishing appropriate prices for any product candidates that receive regulatory approval that reflect the value that the product candidates offer in the indications for which they are approved;
- obtaining and maintaining third-party coverage and reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining an acceptable safety profile of the product candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to commercialize our product candidates successfully, which would materially harm our business. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and may choose to discontinue the development of any of our product candidates. If we discontinue development of a product candidate, we will not receive anticipated revenues from that product candidate and we may not receive any return on our investment in that product candidate. We may discontinue a product candidate for clinical reasons if it does not prove to be safe and effective for its targeted indications. During clinical development, companies in our field often need to discontinue the development of product candidates if such product candidates do not achieve the necessary efficacy at tolerated doses required for patient benefit. In addition, there may be important facts about the safety, efficacy and risk versus benefit of our product candidates that are not known to us at this time. Any unexpected safety events or our failure to generate sufficient data in our clinical trials to demonstrate efficacy may cause a product candidate to fail clinical development. Furthermore, even if that product candidate meets its safety and efficacy endpoints, we may discontinue its development for various reasons, such as changes in the competitive environment or the standard of care and the prioritization of our resources.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business.

An important component of our strategy is expanding our pipeline through partnering, acquiring or in-licensing additional product candidates that target validated biology. We also seek to identify and develop product candidates under our joint ventures with Exscientia Limited, or Exscientia. If we fail to identify additional potential product candidates, or fail to partner, acquire or in-license additional product candidates, our business could be materially harmed.

Research programs to develop additional product candidates require substantial technical, financial, and human resources whether or not they are ultimately successful. Our efforts may initially show promise in identifying potential indications or product candidates, yet fail to yield results for clinical development for several reasons, including:

- the research methodology used may not be successful in identifying potential indications or product candidates;
- potential product candidates may, after further study, be shown to have harmful or unexpected adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through research programs, thereby limiting our ability to develop, diversify, and expand our product portfolio.

Because we have limited financial and human resources, we intend to focus initially on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that could have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

Preclinical studies and clinical trials are expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Any product candidates that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA, EMA or other comparable regulatory authorities for the sale of our product candidates, we must complete preclinical studies and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. To initiate clinical trials for any future product candidates, we must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities, along with other information, including information about chemistry, manufacturing and controls, or CMC, and our proposed clinical trial protocol, as part of an IND or similar regulatory filing that must be accepted by the FDA, EMA or other applicable regulatory authorities before we may proceed with clinical development. In the event that regulators require us to complete additional preclinical studies or we are required to satisfy other regulator requests, such as obtaining alignment on the device regulatory pathway for our FNAIT prevention program, the start of our clinical trials may be delayed or prevented. Even after we receive and incorporate guidance from these regulatory authorities, the FDA, EMA or other regulatory authorities could (i) disagree that we have satisfied their requirements to commence our clinical trial, (ii) change their position on the acceptability of our data, trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or (iii) impose stricter requirements for approval than we currently expect.

We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned preclinical studies or clinical trials, will begin on time, need to be redesigned, enroll an

adequate number of patients on time, or be completed on schedule, or at all. We may experience numerous unforeseen events that could delay or prevent our ability to complete current clinical trials or initiate and complete new trials, any of which may delay or prevent us from receiving marketing approval or commercializing our product candidates. These events include, but are not limited to:

- the FDA, EMA or other comparable foreign regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to commence a trial;
- delays in receiving or denial by regulatory agencies of permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or placement of a clinical trial on hold;
- negative results from our non-clinical trials or clinical trials;
- challenges, delays and cost involved in identifying, recruiting and retaining suitable patients and clinical trial sites in sufficient numbers to participate in clinical trials;
- delays in reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining Institutional Review Board, or IRB, approval at each site within the United States, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- delays or problems in analyzing data, or the need for additional analysis or data or the need to enroll additional patients;
- failure by us, our CROs, trial sites or investigators to adhere to clinical trial, regulatory, legal or contractual requirements and perform trials in accordance with the FDA's good clinical practices, or GCP, requirements and trial protocol;
- inadequate quantity or quality of product candidate or other materials necessary to conduct clinical trials, for example as a result of delays in defining and implementing the manufacturing process for materials used in clinical trials or for the manufacture of larger quantities or other delays or issues arising in the manufacturing of sufficient supply of finished drug product;
- with respect to RLYB211, our inability to source a sustained, dependable long-term supply, including due to the scarcity of potential donors who maintain an adequate level of anti-HPA-1a antibodies and because supply will decrease if RLYB211 becomes clinically successful in preventing FNAIT;
- problems with designing and readiness of in vitro diagnostic devices, including companion diagnostic testing, if required, and our inability, or that of our collaborators, to develop any required laboratory diagnostic tests or companion diagnostics for RLYB212 or any other product candidate;
- lack of adequate funding to continue a clinical trial, including as a result of unanticipated costs or increases in costs of clinical trials;
- occurrence of serious adverse events including unexpected serious adverse events, associated with the product candidate or reports from non-clinical or clinical testing of our own or competing therapies that raise safety or efficacy concerns, or delays or failures in addressing patient safety concerns that arise during the course of a trial;
- changes in regulatory requirements and guidance that require changes to planned or ongoing preclinical and clinical studies, or the conduct of additional studies; and
- difficulties recruiting and retaining employees, consultants or contractors with the required level of expertise.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board, or DSMB, for such trial. Such authorities may impose a suspension or termination or recommend an alteration to clinical trials due to several factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, the identification of safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions. Furthermore, we rely and will rely on CROs and clinical trial sites to ensure the

proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled "— Risks Related to Our Dependence on Third Parties."

Our lead product candidates, RLYB212 and RLYB116, are still in development and will require the successful completion of one or more registrational clinical trials before we are prepared to submit a Biologics License Application, or BLA, for regulatory approval by the FDA. We cannot predict with any certainty if or when we might complete the development of RLYB212 or RLYB116, submit a BLA for regulatory approval or whether any such BLA will be approved by the FDA.

Principal investigators for our clinical trials could serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a clinical trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or prevented. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including our focus on rare diseases.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the speed at which we can recruit eligible patients to participate in testing our product candidates and our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Clinical trial recruitment delays often result in increased costs, delays in advancing product development, delays in testing the effectiveness of technologies, delays in obtaining regulatory approval or termination of clinical trials. We may be unable to enroll a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

Patient enrollment and retention in clinical trials depends on many factors, including:

- the design of the clinical trial, including the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or medical devices that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions, particularly for RLYB116;
- our ability to obtain and maintain patient consents;

- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- other factors we may not be able to control, such as the ongoing COVID-19 pandemic that may limit patients, principal investigators or staff, or clinical site availability.

Additionally, we may have difficulty identifying and enrolling patients for our planned clinical trials because the conditions for which we plan to evaluate our current product candidates are rare diseases and we anticipate that there will be limited patient pools from which to draw for clinical trials. Further, because screening for many of these diseases is not widely adopted, and because it can be difficult to diagnose these diseases in the absence of screening, we may have difficulty finding patients who are eligible to participate in our studies or trials. For example, participants in clinical trials for RLYB211 and RLYB212 have rare HPA-1b genotype and we may have difficulty identifying and receiving consent from a sufficient amount of participants for such clinical trials. In addition, our clinical trials for RLYB116 will compete with other clinical trials for product candidates that are currently being tested in clinical trials for paroxysmal nocturnal hemoglobinuria, or PNH, and generalized myasthenia gravis, or gMG, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, any negative results we may report in clinical trials of any of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same or a similar product candidate.

Outside of the United States, our ability to initiate, enroll and complete a clinical trial successfully is subject to numerous additional risks, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

We may not be able to initiate or continue clinical trials required by the FDA, the EMA or other regulatory authorities if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs or program delays, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible.

Results of preclinical studies, clinical trials or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results.

The results of preclinical studies, clinical trials or analyses of the results from such trials, may not be predictive of the results of later clinical trials. Product candidates in later clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and prior clinical trials or having shown promising results based on analyses of data from earlier trials. Late-stage clinical trials may include a larger number of patients and could differ in other significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, patient population, efficacy endpoints, dosing regimen and statistical design. Our Phase 1/2 clinical trial for RLYB211 is single blinded, making it difficult to predict how rapid platelet clearance will lead to prevention of alloimmunization in pregnant women at higher risk for FNAIT and whether any favorable results that we may observe in such trial will be repeated in larger and more advanced clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and post hoc analysis of results may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. We believe data from our Phase 1/2 clinical trial of RLYB211 has demonstrated proof of concept of our proposed mechanism of action and supports advancing RLYB212 into clinical trials, however, we cannot guarantee that clinical trial results will be similar for RLYB212. Even if we complete later clinical trials as

planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

In addition, interim, “top-line” and preliminary data from our clinical trials that we announce or publish may change as more patient data become available or as additional analyses are conducted. The data obtained in such clinical trial are subject to additional audit and verification procedures and following such procedures, such interim data could be materially different from the final data.

Any product candidates that we develop or the administration thereof, may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales.

Adverse events or undesirable side effects caused by any product candidates we develop could cause us or regulatory authorities or IRBs, IECs or DSMBs, where applicable, to interrupt, delay, or halt clinical trials and, if we seek approval of any such product candidate, could result in a more restrictive label, imposition of a Risk Evaluation and Mitigation Strategy, or REMS, program by the FDA or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, the administration process or related procedures associated with our product candidates also may cause adverse side effects. Even if we determine that serious adverse events are unrelated to study treatment, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects. For example, complement inhibitors have, by design, immunosuppressive effects and, in some cases, may be administered to patients with significantly compromised health. As a result, administration of RLYB116 could make patients more susceptible to infection. The chronic dosing of patients with RLYB116 could lead to an immune response that causes adverse reactions or impairs the activity and/or efficacy. Patients may develop an allergic reaction to the drug and/or develop antibodies directed at RLYB116, or may require immunization with a meningococcal vaccine and prophylactic antibiotics. An immune response that causes adverse reactions or impairs the activity of RLYB116 could cause a delay in or termination of our development plans.

Some potential therapeutics that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential clinical trial or product liability claims. Inadequate training or failures by clinical trial personnel in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered when a significantly larger number of patients have been exposed to the drug.

If we or others later identify undesirable side effects caused by any product candidate that we develop after the product is approved, several negative consequences could result, which could materially harm our business, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label, limit the approved use of such product candidate, or otherwise restrict distribution or marketing such as through requiring adoption of a REMS program;
- we may be required to conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for RLYB212, RLYB116 or any of our other product candidates, our business will be substantially harmed.

In the United States, we are not permitted to market a product candidate until we receive approval of a BLA or a New Drug Application, or NDA, from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change, and the FDA and other regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. In addition, the FDA may require post-approval clinical trials or studies as a condition of approval, which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. The FDA also may require adoption of a REMS requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. The FDA may inform us that an approved device, including a companion diagnostic, is required to obtain marketing approval of RLYB212. Companion diagnostics are subject to regulation as medical devices and must be separately approved for marketing by the FDA. Certain of our product candidates will rely on delivery systems, such as PFSs, pen-injectors and/or autoinjectors, and may ultimately be regulated as a drug/device combination product. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed for our product candidates or a companion diagnostic, if required. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States, including in Europe. As a result, we would be subject to regulation by the EMA, as well as the other regulatory agencies in these countries.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates and we may be forced to abandon our development efforts for our product candidate, which would significantly harm our business, results of operations, and prospects.

The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for any product candidate.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate to the satisfaction of the FDA, EMA or other comparable foreign regulatory authority, that such product candidates are safe and effective for their intended uses. Data obtained from preclinical studies and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit, or prevent development efforts, clinical trials, or marketing approval. Even if we believe the preclinical or clinical data for our product candidates are sufficient to support approval, such data may not be considered sufficient to support approval by the FDA, EMA and other comparable regulatory authorities.

For example, we have proposed to use real-world data from our FNAIT Natural History Alloimmunization Study to support our development program and related regulatory submissions for RLYB212. Specifically, the natural history study data would assist us in assessing the frequency of women at higher risk of FNAIT among women of different racial and ethnic characteristics and the occurrence of HPA-1a alloimmunization in these women. The natural history studies and other real-world evidence we may submit to support applications for marketing approval may not be accepted by the FDA, EMA, or other comparable foreign regulatory authorities.

The FDA, EMA or other comparable foreign regulatory authority can delay, limit, or deny approval of RLYB212, RLYB116 or any of our other product candidates that we develop or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including, but not limited to:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities that our product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing an active ingredient in our product candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, EMA or other comparable foreign regulatory authorities for approval;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States or the applicable foreign jurisdiction;
- we may be unable to demonstrate that our product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or NDA or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of our product candidates;
- the FDA, EMA, or other comparable foreign regulatory authorities may require us to obtain clearance or approval of a companion diagnostic test;
- additional time may be required to obtain regulatory approval for our product candidates because they are combination products;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any BLAs or NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our BLAs or NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or NDA that we submit may be delayed or prevented, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our BLA or NDA. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability.

Our product candidates target rare diseases and conditions, and the market opportunities for RLYB212 and RLYB116, if approved, may be smaller than we anticipate. As a result, our commercial opportunity may be limited and because the target populations of our product candidates are for rare diseases, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

Our product candidates target rare diseases and conditions. We are developing RLYB212 for the potential prevention of FNAIT, and we estimate that each year greater than 22,000 pregnancies are at high risk for FNAIT in the United States, Canada, United Kingdom, other major European countries and Australia, based on the presence of HLA DRB3*01:01 positive and HPA-1a negative antibody in mothers and HPA-1a positive in the fetus. With respect to RLYB116, we estimate that there are approximately 4,700 patients with PNH and up to 60,000 patients with gMG in the United States. Our projections of the number of eligible patients are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, population statistics and market research, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of eligible patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to. For example, even if we obtain FDA approval for RLYB212 or RLYB116, the drug may be approved for a target population that is more limited than what we currently anticipate. Furthermore, even if we obtain significant market share for any product candidate, if approved, the potential target populations for our product candidates are for rare diseases, and we may never achieve profitability.

Further, in many cases there are either no or limited screening or diagnostic tests for the indications our product candidates are being developed to potentially treat. For example, the successful prevention of FNAIT in mothers at risk for developing this rare disorder will require identifying expectant mothers who are HPA-1 negative and HLA DRB3*01:01 positive and HPA-1a positive in the fetus. In collaboration with partners, we may develop screening and diagnostics tests to help us to identify individuals at risk, and the FDA, EMA or other comparable foreign regulatory authorities may require us to do so. The lack of screening and diagnostic tests, coupled with the fact that there is frequently limited awareness among certain health care providers concerning the rare diseases we may seek to treat, often means that a proper diagnosis can, and frequently does, take years to identify (or an appropriate diagnosis may never be made for certain patients). As a result, even if one of our product candidates is approved for commercial sale, we may not be able to grow our revenues due to difficulty in identifying eligible patients. There can be no guarantee that any of our programs will be effective at identifying patients that will benefit from our product candidates, and even if we can identify patients that our product candidates can help, the number of patients that our product candidates may ultimately treat may turn out to be lower than we expect, they may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify, all of which may adversely affect our ability to grow and generate revenue and adversely affect our results of operations and our business. In addition, even in instances where we are able to expand the number of patients being treated, the number may be offset by the number of patients that discontinue use of the applicable product in a given period resulting in a net loss of patients and potentially decreased revenue.

The FDA, EMA or other comparable foreign regulatory authorities could require the clearance or approval of an in vitro diagnostic or companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy and we may not realize the commercial potential of any such product candidate.

If safe and effective use of RLYB212 or any of our other product candidates depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that test, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of development and approval of such diagnostic is time consuming and costly. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA, EMA and other comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro diagnostic tests intended to select the patients who will respond to a product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the

applicant must prepare and provide FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.

Given our limited experience in developing and commercializing in vitro diagnostic devices, including companion diagnostic tests, we do not plan to develop such tests internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these in vitro diagnostic tests. We may not be able to enter into arrangements with a provider to develop screening and/or diagnostic tests for use in connection with a registrational trial for RLYB212 or for commercialization of RLYB212, or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of RLYB212. We and our future collaborators may encounter difficulties in developing and obtaining approval for the such tests, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of in vitro diagnostic tests could delay or prevent approval of RLYB212 or any of our other product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of such tests, and both they and we may have difficulties gaining acceptance of the use of such tests by physicians. We believe that adoption of screening and treatment into clinical practice guidelines is important for market access, third-party payer reimbursement, utilization in medical practice and commercial success. Both our collaborators and we may have difficulty gaining acceptance of such screening and/or diagnostic tests into clinical practice guidelines. If such tests fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales, if any, of RLYB212 if it is approved for commercial sale, or any other approved products that require an in vitro diagnostic test. In addition, any collaborator or third-party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the test that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with such collaborator or third-party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative in vitro diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

We face significant competition from biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a product candidate we develop is approved, we will face intense competition. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development of products that may be like our product candidates or address similar markets. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. We believe RLYB212 could be a first-in-class antibody for the prevention of FNAIT, and no direct mechanistic based clinical competition currently exists. Our second product candidate, RLYB116 faces competition from a number of companies for the treatment of patients with PNH and gMG, including Soliris and Ultomiris marketed by Alexion Pharmaceuticals, Inc., or Alexion. If we successfully develop and, if approved, commercialize RLYB116, this therapy may compete, or potentially be used in conjunction, with currently marketed treatments, including Soliris and Ultomiris, and any new therapies that may become available in the future. See "Business—Competition."

Competition could render any product candidate we develop obsolete, less competitive, or uneconomical. In addition, product candidates developed by our competitors may prove to be more safe or more effective than our product candidates. Our competitors may, among other things:

- have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, commercial infrastructure, and human resources than we do;
- more effectively recruit and retain qualified scientific and management personnel;
- more effectively establish clinical trial sites and patient registration;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- better protect their patents and intellectual property or acquire technologies that are complementary to, or necessary for, our programs;
- implement more effective approaches to sales, marketing, pricing, coverage, market access, and reimbursement; or
- form more advantageous strategic alliances or collaborations.

If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

Disruptions in the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In April 2021, the FDA released additional guidance on its handling of inspections during the COVID-19 pandemic, addressing situations where FDA may request to conduct a remote interactive evaluation. While participation in a remote interactive evaluation is voluntary, declining FDA's guidance could impede the FDA's ability to make a timely regulatory decision (e.g., regarding adequacy of a clinical trial used in support of a pending application or adequacy of a drug manufacturing operation described in the application). Regulatory authorities outside the United States may also impose similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain FDA approval for a product candidate in the United States, we or our current or future collaborators may never obtain approval for or commercialize the product candidate in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market any product in a particular jurisdiction, we or our current or future collaborators must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a country-by-country basis. Approval by the FDA in the United States does not ensure approval by comparable regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our or our collaborators' ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time- consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and we will be unable to realize the full market potential of any product we develop.

Even if we obtain regulatory approval for any of our product candidates, we will still face extensive and ongoing regulatory requirements and obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product candidates.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval preclinical and clinical testing, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements regarding the distribution of samples to physicians and recordkeeping and Good Laboratory Practice, or GLP, and GCP requirements for non-clinical studies and any clinical trials that we conduct post-approval.

The FDA may also require costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Additionally, the FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in a manner that is consistent with the provisions of the approved labeling. If we market our products for uses beyond their approved indications or otherwise inconsistent with the FDA-approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including, but not limited to:

- restrictions on manufacturing such products;
- restrictions in the labeling or on the marketing of products;
- restrictions on product distribution or use;

- requirements to conduct post-marketing studies or additional post-marketing clinical trials;
- issuance of warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit, or delays in such approvals;
- recalls or market withdrawals of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or termination of ongoing clinical trials;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

If we obtain FDA approval for RLYB212 or RLYB116, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize these product candidates. Any new post-marketing adverse events may significantly impact our ability to market the drugs and may require that we recall and discontinue commercialization of the products. Furthermore, if any confirmatory post-marketing trial fails to confirm the clinical profile or clinical benefits of RLYB212 or RLYB116, the FDA may withdraw its approval, which would materially harm our business.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Further, the FDA's, EMA's and other comparable regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a product candidate or increase the costs and regulatory burden of commercialization. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, non-compliance by us or any collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.

We may seek Fast Track designation, Breakthrough Therapy designation, or PRIME designation for our product candidates, but we might not receive any such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening condition, and non-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product candidate may qualify for FDA Fast Track designation, for which sponsors must apply. Sponsors of fast track products may have more frequent interactions with the FDA, and, in some circumstances, the FDA may initiate review of sections of a fast track product's application before the application is complete. We may submit an application for Fast Track designation for RLYB212 and RLYB116. The FDA has broad discretion whether to grant this designation, and we may not receive it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We also may seek a Breakthrough Therapy designation for RLYB212 or other product candidates if future results support such designation. A Breakthrough Therapy is defined as a drug (including biologic) that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of products that have been designated as breakthrough therapies are eligible to receive more intensive FDA guidance on establishing an efficient drug development program, an organization commitment involving senior managers, and may be eligible

for rolling review. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited review programs, including accelerated approval and priority review, if supported by clinical data at the time the BLA or NDA is submitted to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that RLYB212 meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if RLYB212 qualifies as a Breakthrough Therapy, the FDA may later decide that RLYB212 no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union, or EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that can substantiate the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as RLYB212 and RLYB116 or any of our other product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and the EU. may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of more than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products evaluates, and the European Commission grants, an orphan drug designation principally to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In addition, the product under consideration is indicated for a condition where there exists no satisfactory method of diagnosis, prevention or treatment authorized in the EU or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. Each of the FDA and the European Commission has granted orphan drug designation for RLYB211 and RLYB212 for the treatment of FNAIT. We may seek orphan drug designation in the United States and the EU for our other product candidates but may be unsuccessful in doing so. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will consider orphan designation for any indication for which we apply or re-apply, or that we will be able to maintain such designation. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding

towards clinical trial costs, tax advantages and user-fee waivers. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

If a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the same orphan designation for that time period, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the United States, the exclusivity period is seven years. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years in Europe if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Similarly, in the EU, the market exclusivity can be broken if the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product. In addition, in both the United States and EU, if a different drug is subsequently approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity, which only protects against approval of the “same” drug for the same indication.

We may seek accelerated approval by the FDA for one or more of our product candidates. Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform a post-marketing confirmatory clinical trial or trials. In addition, the FDA currently requires as a condition for accelerated approval the pre-submission of promotional materials to FDA for review.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval there can be no assurance that such submission or application will be accepted or that the FDA will determine that the product candidate is eligible for or grant accelerated approval. A failure to obtain any planned accelerated approval for our product candidates would result in a longer time period to commercialization of our product candidates, if approved, could increase the cost of development of our product candidates and could harm our competitive position in the marketplace. If we receive accelerated approval for any of our product candidates, the FDA may withdraw accelerated approval if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence. Withdrawal of any accelerated approval could substantially harm our business.

Although RLYB211 and RLYB212 have received FDA designation as rare pediatric disease drug products, any marketing application we submit for these products may not qualify for issuance of a rare pediatric disease priority review voucher.

In the United States, RLYB211 and RLYB212 have received designation from the FDA as rare pediatric disease drug products. Receipt of rare pediatric disease designation is a prerequisite to qualifying for receipt of a rare pediatric disease priority review voucher upon approval of a marketing application for the rare pediatric disease drug product. The priority review voucher may be used to obtain priority review of a future marketing application that would not otherwise qualify to receive priority review. Priority review shortens the FDA’s goal for taking action on a marketing

application from ten months to six months for an original BLA or NDA from the date of filing. As an alternative to using the priority review voucher to obtain priority review of one of its own marketing applications, the sponsor of a rare pediatric disease drug product receiving a priority review voucher may also sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

There is no guarantee that, if we ever submit and obtain approval for RLYB211 or RLYB212 or any other product candidate for which we may obtain rare pediatric disease designation in the future, we will receive a rare pediatric disease priority review voucher. In addition to receiving rare pediatric disease designation, in order to receive a rare pediatric disease priority review voucher, the NDA or BLA must be granted priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a drug that does not include a previously approved active ingredient. Under current statutory sunset provisions, even if a marketing application meets all of these requirements, FDA may only award a voucher prior to September 30, 2026 and only if the approved product received rare pediatric disease drug product designation prior to September 30, 2024. We cannot be certain that we will receive approval for any of our rare pediatric disease designated products prior to the statutory sunset date, if ever. Moreover, even if we believe that our marketing application meets the other requirements to be eligible to receive a priority review voucher upon approval, FDA may disagree.

The successful commercialization of any product candidate we develop will depend in part on the extent to which regulatory authorities and private health insurers establish coverage and reimbursement. Failure to obtain or maintain coverage and reimbursement for our product candidates, if approved, could limit our or our collaborators' ability to market those products and decrease our or our collaborators' ability to generate revenue.

Our ability to obtain coverage and reimbursement for any product candidates by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, and other third-party payors is essential for most patients to be able to afford prescription medications. Our ability to achieve acceptable levels of coverage and reimbursement for products or procedures using our products by regulatory authorities, private health insurers and other third-party payors will therefore have an effect on our ability to successfully commercialize any product candidates we develop. We cannot be sure that coverage and reimbursement will be available for our product candidates, if and when such candidates obtain marketing approval, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause third-party payors to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for any product we commercialize. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care and additional legislative, administrative, or regulatory changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense and new products face increasing challenges in entering the market successfully. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any current or future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and reimbursement will be obtained or will be

consistent across payors. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

We or our collaborators may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we or our collaborators are able to charge for products we or our collaborators commercialize. Accordingly, in markets outside the United States, the reimbursement for products we or our collaborators commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Even if a product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Commercial success also will depend, in large part, on the coverage and reimbursement of our product candidates and associated screening and/or diagnostic tests by third-party payors, including private insurance providers and government payors. Various factors will influence whether our product candidates are accepted in the market if approved for commercial sale, including, but not limited to:

- the efficacy, safety and tolerability of our products, and potential advantages compared to alternative treatments;
- the clinical indications for which the product is approved, and product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the effectiveness of sales and marketing efforts;
- the prevalence and severity of any side effects;
- the cost of treatment in relation to alternative treatments, including any similar treatments;
- our ability to offer our products for sale at competitive prices;
- the availability and access to screening and/or diagnostic tests;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and reimbursement for any of our products that are approved and any screening and/or diagnostic testing, as appropriate; and
- any restrictions on the use of our product together with other medications.

Market acceptance of our product candidates is heavily dependent on patients' and physicians' perceptions that our product candidates are safe and effective treatments for their targeted indications and willingness to use screening and/or diagnostic tests to identify at-risk target populations for our therapeutics. The perceptions of any product are also influenced by perceptions of competitors' products that are in the same class or that have a similar mechanism of action. Because we expect sales of our product candidates, if approved, to generate substantially all our revenues in the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If approved, our product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, or the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and

approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product, sponsor’s data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If the FDA, EMA or other comparable foreign regulatory authorities approve generic versions of any of our small molecule investigational products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our products are approved, even if we still have patent protection for such products. Competition that our products could face from generic versions of our products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any product candidates we develop, if approved.

In order to market and successfully commercialize any product candidates we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently

have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. If we commercialize any of our product candidates that may be approved ourselves, we will need to develop an in-house marketing organization and sales force across rare disease therapeutic areas, which will require significant expenditures, management resources, and time. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retrain marketing and sales personnel. Any failure or delay in the development of a product candidate that affects the expected timing of commercialization of the product candidate or results in the failure of the product candidate to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses. Our investment would be lost if we are unable to retain or reposition our sales and marketing personnel.

We may also enter into collaborations for the sales and marketing of our product candidates, if approved. To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of those collaborators' sales and marketing teams and the collaborators' prioritization of our products and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful. If we are unable to build our own sales and marketing team or enter into a collaboration for the commercialization of product candidates we develop, if approved, we may be forced to delay the commercialization of our product candidates or reduce the scope of our sales or marketing activities, which would have an adverse effect on our business, operating results and prospects.

Risks Related to Our Dependence on Third Parties

We intend to continue to acquire or in-license rights to additional product candidates or collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

We acquired all rights to RLYB211 and RLYB212 from Prophylix in 2019 and rights to RLYB116 and RLYB114 from Sobi in 2019. We also have entered into joint ventures with Exscientia for the development of small molecule therapeutics for rare diseases. An important component of our approach to product development is to acquire or in-license rights to product candidates, products or technologies, acquire other businesses or enter into collaborations with third parties. We may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions, in-licenses or collaborations may not strengthen our competitive position, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to incur debt in connection with an acquisition, or in-license or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

We may not realize the anticipated benefits of any current or future collaboration, each of which involves or will involve numerous risks, including:

- a collaborator may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale, or downsizing;
- a collaborator may seek to renegotiate or terminate its relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;

- a collaborator may cease development in therapeutic areas that are the subject of our collaboration;
- a collaborator may not devote sufficient capital or resources towards our product candidates, or may fail to comply with applicable regulatory requirements;
- a collaborator may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our product candidates;
- a collaborator with commercialization obligations may not commit sufficient financial resources or personnel to the marketing, distribution, or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaborator may terminate a strategic alliance;
- a dispute may arise between us and a collaborator concerning the research, development, or commercialization of a product candidate resulting in a delay in milestones or royalty payments or termination of the relationship and possibly resulting in costly litigation or arbitration, which may divert management's attention and resources; and
- a collaborator may use our products or technology in such a way as to invite litigation from a third-party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborations on acceptable terms or to successfully transition away from terminated collaborations, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense, or find alternative sources of capital, which would have a material adverse impact on our clinical development plans and business. If we fail to establish and maintain collaborations related to our product candidates, we could bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise for which we have not budgeted. This could negatively affect the development and commercialization of our product candidates.

We may face significant competition in identifying and acquiring businesses or assets, in-licensing intellectual property rights and seeking appropriate collaboration partners for our product candidates, and the negotiation process may be time-consuming and complex. In order for us to successfully partner our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products or product candidates available for licensing from or in connection with collaborations with other companies. Our success in acquiring business or assets or in partnering with collaborators may depend on our history or perceived capability of successful product development. Even if we are successful in our efforts to acquire businesses or assets, in-license intellectual property rights or establish collaborations, we may not be successful in developing such products candidates or technologies or able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

Our reliance on a central team consisting of a limited number of employees and third parties who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

As of March 31, 2021, we had 22 full-time employees, upon whom we rely for various administrative, research and development, business development and other support services shared among our subsidiaries and the Exscientia joint venture. The size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries and the Exscientia joint venture, including their research and development activities, the management of financial, accounting, and reporting matters, and the oversight of our third-party vendors and partners. If our centralized team or our third party vendors and partners

performing such functions fail to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these or other laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely and will rely on third parties for the manufacture of drug substance for our preclinical studies and clinical trials and expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. We also rely and will rely on third parties for the design and manufacture of companion diagnostics related to RLYB212 and any other product candidates that may require a companion diagnostic. Our reliance on third parties may increase the risk that we will not have sufficient quantities of such drug substance, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing RLYB211, RLYB212 and RLYB116 or any other product candidate. Instead, we rely on and expect to continue to rely on contract manufacturers for the supply of cGMP-drug substance and drug product of RLYB211, RLYB212 and RLYB116 and any other product candidates we develop and, in the future, for commercial supply. Reliance on third parties may expose us to more risk than if we were to manufacture our product candidates ourselves.

We may be unable to establish necessary supply agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third-party;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- reliance on the third-party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and

- the possible inability of third-party suppliers to supply and/or transport materials, components and products to us in a timely manner as a result of disruptions to the global supply chain, including in connection with the COVID-19 pandemic.

Third-party manufacturers may fail to comply with cGMP regulations or similar regulatory requirements outside the United States. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Moreover, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

While we provide oversight of manufacturing activities, we have limited ability to control the execution of manufacturing activities by, and are or will be dependent on, our contract manufacturing organizations, or CMOs, for compliance with cGMP requirements for the manufacture of our product candidates by our CMOs. As a result, we are subject to the risk that our product candidates may have manufacturing defects or fail to comply with regulatory requirements, which we have limited ability to prevent. CMOs may also have competing obligations that prevent them from manufacturing our product candidates in a timely manner. If a CMO cannot successfully manufacture drug substance that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we were not involved in developing our CMOs' policies and procedures.

The facilities and processes used to manufacture our product candidates are subject to inspection by the FDA, EMA and other comparable foreign authorities. If the FDA, EMA or other comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities or conduct additional studies, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We have limited ability to control the process or timing of the acquisition of these raw materials by our CMOs. The COVID-19 pandemic may also have an impact on the ability of our CMOs to acquire raw materials. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw materials could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product

candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. Moreover, our product candidates utilize drug substances that are produced on a small scale, which could limit our ability to reach agreements with alternative suppliers.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. Further, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

In addition, given our limited experience in developing and commercializing companion diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for companion diagnostics if required. Reliance on these third-party collaborators exposes us to risks due to our limited control of their activities, including compliance by them with cGMP regulations or similar foreign requirements and inspection of their manufacturing facilities by the FDA or comparable foreign regulatory authorities and their obtaining, maintaining and protecting their intellectual property rights necessary to develop and manufacture companion diagnostics while not infringing on the intellectual property rights of others. We or our third-party collaborators also will need to source raw materials for any companion diagnostics, including obtaining amounts sufficient for widespread adoption of testing and a potential commercial launch of RLYB212, if approved, and we may be dependent on our collaborators to identify and obtain reliable sources of raw materials. Our collaborators also may breach their agreements with us or otherwise fail to perform to our satisfaction, which could impact the development timeline of our product candidates, and we may incur additional costs and delays if we need to transition to a new third-party companion diagnostic partner.

We rely, and will continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If we fail to effectively oversee and manage these third parties, if they do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards.

We and our CROs will be required to comply with the GLP requirements for our preclinical studies and GCP requirements for our clinical trials. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we, or our CROs, fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements and may require a large number of patients. Our failure or any failure by our CROs, investigators, CMOs or other third parties to comply with regulatory requirements or to recruit enough patients may delay ongoing or planned clinical trials or require us to repeat clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs, vendors and clinical trial investigators are not our employees, and we do not control whether they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized

disclosure or misappropriation of our intellectual property by CROs and other third parties involved in our preclinical studies and clinical trials, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs and other third parties involved in our trials do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidates that we develop. As a result, our financial results and the commercial prospects for any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes, and additional proposed changes, to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of health care. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. The ACA expanded health care coverage through a Medicaid expansion and the implementation of the individual mandate for health insurance coverage. The ACA also imposed an annual fee payable on manufacturers of branded prescription drugs and biologic agents (other than those designated as orphan drugs) and included changes to the coverage and reimbursement of drug products under government healthcare programs. Such changes included an expansion in the Medicaid drug rebate program and an increase in the statutory minimum rebates a manufacturer must pay under the program as well as a new Medicare Part D coverage gap discount program requiring manufacturers to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period in exchange for coverage of the drugs under Medicare Part D. Under the Trump administration, there were ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under the ACA for individuals who do not maintain the mandated health insurance coverage beginning in 2019. The ACA has also been subject to judicial challenge. The case Texas v. Azar, which challenges the constitutionality of the ACA, including provisions that are unrelated to healthcare reform but were enacted as part of the ACA, was argued before the Supreme Court in November 2020. The Supreme Court is expected to issue a decision sometime in 2021. Pending resolution of the litigation, all of the provisions in the ACA but the individual mandate to buy health insurance remains in effect.

Beyond the ACA, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare, accelerated or advanced Medicare payments to healthcare providers and payments to providers for COVID-19-related expenses and lost revenues. Other reform efforts affect pricing or payment for drug products, which was a focus of the Trump Administration. For example, subsequent to the ACA, the Medicaid Drug Rebate Program was subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. Several regulations were issued in late 2020 and early 2021, some of which have been and may continue to be subject to scrutiny and legal challenge. For example, courts temporarily enjoined a new "most favored nation" payment model for select drugs covered under Medicare Part B that was to

take effect on January 1, 2021 and would limit payment based on international drug price, and the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services, or CMS, subsequently indicated that the rule will not be implemented without further rulemaking. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to PBMs and health plans. The revisions to the federal anti-kickback statute regulations referenced above were initially scheduled to take effect in 2022 but have now been delayed to 2023.

The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain but early actions suggest additional changes as well as challenges to actions taken under the Trump administration. The Department of Justice under the Biden administration informed the Supreme Court in connection with case Texas v. Azar, that the government no longer takes the position that the individual mandate is unconstitutional and cannot be severed from the rest of the ACA. President Biden temporarily halted implementation of new rules that were issued immediately prior to the transition from the Trump administration to the Biden administration that had not yet taken effect (which include a number of health care reforms) to allow for review by the new administration. By Executive Order, President Biden directed federal agencies to reconsider rules and other policies that limit Americans' access to health care and consider actions that will protect and strengthen that access. President Biden supported reforms to lower prescription drug prices during his campaign for the presidency. The American Rescue Plan Act of 2021, comprehensive COVID-19 relief legislation recently enacted under the Biden administration, include a number of healthcare-related provisions, such as support to rural health care providers, increased tax subsidies for health insurance purchased through insurance exchange marketplaces, financial incentives to states to expand Medicaid programs and elimination of the Medicaid drug rebate cap effective in 2024.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2030 (except May 1, 2020 to December 31, 2021) unless additional Congressional action is taken. The Congressional Budget Office has indicated that the American Rescue Plan Act of 2021 will likely trigger a statutory provision that requires that automatic payment cuts be put into place if a statutory action creates a net increase in the deficit and require reductions in Medicare spending. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been administration efforts, Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be implemented in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. Furthermore, there has been

increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we, or any third parties we may engage, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws, some of which may apply only after our products are approved for marketing, include:

- U.S. federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- U.S. the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- U.S. FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to regulatory authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- U.S. federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the CMS for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the General Data Protection Regulation, or GDPR, which

imposes obligations and restrictions on the collection, use, and disclosure of personal data relating to individuals located in the EU and the European Economic Area, or EEA, (including health data). See "—Our business operations may subject us to data protection laws, including the GDPR, the United Kingdom GDPR, the California Consumer Privacy Act and other similar laws"; and

- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, regulatory authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations, including our consulting agreements and other relationships with healthcare providers.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our business operations may subject us to data protection laws, including the GDPR, the United Kingdom GDPR, the California Consumer Privacy Act and other similar laws.

The GDPR applies to companies established in the EEA, as well as to companies that are not established in the EEA and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. If we conduct clinical trial programs in the EEA (whether the trials are conducted directly by us or through a clinical vendor or collaborator), or enter into research collaborations involving the monitoring of individuals in the EEA, or market our products to individuals in the EEA, we will be subject to the GDPR. The GDPR puts in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a concise, intelligible and easily accessible form), an individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA, short timelines for data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches, and limitations on retention of information. The GDPR also puts in place increased requirements pertaining to health data and other special categories of personal data, as well as a definition of pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third-party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros or up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

Further, from January 1, 2021, we may also have to comply with the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR with fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes could lead to additional costs and increase our overall risk exposure.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the United Kingdom to the United States. Most recently, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer.

These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. While we do not believe that we are directly subject to HIPAA as either a “covered entity” or “business associate,” U.S. sites at which we conduct clinical trials are likely to be covered entities and thus must ensure that they obtain adequate patient authorization or establish another basis under HIPAA to disclose a clinical trial subject’s individually identifiable health information to us and other entities participating in our clinical trials.

In the United States, The California Consumer Privacy Act, or the CCPA, came into effect in January 2020 and, among other things, requires new disclosures to California individuals and affords such individuals new abilities to opt out of certain sales of personal information, and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Because we have not yet generated revenue and do not meet the CCPA’s other jurisdictional tests, we do not yet meet the applicable threshold for CCPA to apply to our business. If our business becomes subject to CCPA in the future, it could increase our compliance

costs and potential liability. Further, the California Privacy Rights Act, or the CPRA, recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, though the obligations for covered businesses will apply to any personal information collected after January 1, 2022. Similar laws have been proposed or passed at the U.S. federal and state level, including the Virginia Consumer Data Protection Act, which will take effect on January 1, 2023. We will need to review periodically our operations in comparison to developments in such laws.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and select other countries related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain or maintain patent protection in jurisdictions important to our business with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In some circumstances involving technology that we license from third parties, we do not have the sole right to control the preparation, filing and prosecution of patent applications or to maintain, enforce and defend the in-licensed patents. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent rights of pharmaceutical and biotechnology companies generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged in the U.S. or in numerous foreign jurisdictions. Various courts, including the United States Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These

decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter. Precisely what constitutes a law of nature or abstract idea is uncertain, and certain aspects of our technology could be considered ineligible for patenting under applicable law. In addition, the scope of patent protection outside the United States is uncertain, and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law precludes the patentability of methods of treatment of the human body. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents that protect our technology and product candidates, in whole or in part, in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights.

Further, third parties may have intellectual property rights relating to our product candidates of which we are unaware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are uncertain.

We, or our licensors, may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others in the United States and/or foreign countries. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For these reasons, our owned and in- licensed patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of our technology and product candidates for any period of time.

Patent terms may not protect our competitive position for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and

regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours during periods when commercial exclusivity would be valuable to us.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, which if granted could extend the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a PTE of up to five years beyond the expiration date of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, the patent term of only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for PTEs on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted and, even if granted, the length of such extensions. We may not be granted PTE either in the United States or in any foreign country, even where that patent is eligible for PTE, if, for example, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the regulatory authority could be less than we request. If we obtain such an extension, it may be for a shorter period than we had sought. If we are unable to obtain any PTE or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Furthermore, for any future licensed patents, we may not have the right to control prosecution, including filing with the USPTO or any foreign agency, of a petition for PTE under the Hatch-Waxman Act or analogous foreign provisions. Thus, for example, if one of our licensed patent applications, if granted, is eligible for PTE under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a PTE is filed, or obtained from the USPTO.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States or other jurisdictions, including patent reform legislation such as the U.S. Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that switched the United States from a first- to-invent system to a first-inventor-to-file system, affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents and enable third-party submission of prior art to the USPTO during patent prosecution, and provide additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, under the Leahy-Smith Act and pursuant to foreign laws outside of the United States, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. Such laws could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in

certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

We may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property that we or our licensors may own, obtain or acquire. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property claims, which can be expensive and time-consuming. Any claims we assert against others could provoke them to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. In a patent infringement proceeding, the perceived infringers could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings in the European Patent Office. The outcomes of allegations of invalidity or unenforceability are unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution.

An adverse result in any such proceeding could put one or more of our current or future owned or in- licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in- licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding, for example, on the basis that our owned or in-licensed patents do not cover that technology. Furthermore, if the breadth or strength of protection provided by our current or future patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products, diagnostic tests, or services.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during litigation. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, future litigation may be initiated by patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Because patent applications can take many years to issue, pending patent applications may result in issued patents that our product candidates infringe. For example, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of our product candidates or technologies. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property rights.

A court could hold that third-party patents are valid, enforceable and infringed. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one that requires us to present clear and convincing evidence as to the invalidity of the claims of any such United States patent, there is no assurance that a court would invalidate the claims of any such United States patent.

Parties making claims against us may obtain injunctive or other equitable relief. For example, if any third-party patents were held to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates. In the event of a successful claim of infringement against us, we may also have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, collaborators or other third parties, seek new regulatory approvals, and redesign our infringing products, which may not be possible or practical. If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we may be required to obtain a license from such third-party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities, which would impair our ability to pursue our business. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our adversaries may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and prosecution process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms, and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the current and future patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms, our business could be harmed.

In addition to our existing licensing agreements, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, if approved, in which case we would be required to obtain a license from these third parties. The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, such as substantial licensing or royalty payments, our business could be materially harmed. If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our sales or we may be unable to otherwise develop or commercialize the affected product candidates, which could materially harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

If we fail to comply with our obligations in our intellectual property licenses with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to license agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, among other things, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing agreements, including our license agreement with Affibody, we are obligated to pay milestones and royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements, or our counterparties may require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects, or impede, delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements.

Disputes may arise regarding intellectual property that is or becomes subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other matters of contract interpretation;
- whether and the extent to which our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- the sublicensing of patent and other rights under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have

licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Despite our efforts, our licensors or future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors could seek regulatory approval for and market products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to develop and commercialize competitive products in foreign countries where we do not have any patent protection and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling our inventions in such countries or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent as the United States or at all, inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries, including India, China and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor, co-inventor, owner or co-owner. For example, we or our licensors or collaborators may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' or collaborators' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors or collaborators fail in defending any such claims, we may be required to pay monetary damages and we may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of such third parties, or that they have wrongfully used or disclosed alleged trade secrets of their current or former employers, or that we have misappropriated their intellectual property, or that they own what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Many of them executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such previous employment or engagement. Although we try to ensure that the individuals who work for us do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or they have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights, or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. We may also be subject to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. Any litigation or the threat of litigation may adversely affect our ability to hire employees or engage consultants and contractors. A loss of key personnel or their work product could hamper or prevent us from developing and commercializing products and product candidates, which could harm our business.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract

manufacturers, consultants, advisors and other third parties. We also enter into confidentiality agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us.

Furthermore, we expect that, over time, our trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These security measures may be breached, and we may not have adequate remedies for any breach.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain a competitive advantage. For example:

- we or our license partners or current or future collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we cannot ensure that any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to seek patent protection in order to maintain certain trade secrets or know- how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Employees, Managing Our Growth and Our Operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of the principal members of our management, scientific, and clinical teams. Our scientific and clinical development personnel have extensive experience developing and implementing novel clinical trial designs and successfully conducting clinical trials in never-before treated patient populations. If we lose one or more of our executive officers or key employees, our ability to execute our programs and implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We may also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

Many of our employees were previously employed by Alexion, a potential competitor. To the extent we employ or engage personnel from competitors, we may be subject to allegations that such individuals have been improperly solicited or have divulged proprietary or other confidential information, or that their former employers own their research output.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or lease or acquire new facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and

may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters (including hurricanes), terrorism, war, and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure or accident to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials, or the loss of other proprietary data, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, and the development of our product candidates could be delayed.

Our proprietary or confidential information may be lost, or we may suffer security breaches.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions. Several proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors, or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored therein could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay the clinical development of our product candidates.

Risks Related to this Offering and Our Common Stock

We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- the success of the development of companion diagnostics, if required, for use with our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- effects of public health crises, pandemics and epidemics, such as COVID-19;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section and elsewhere in this prospectus.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

You will incur immediate and substantial dilution as a result of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma net tangible book value per share after giving effect to this offering. To the extent that shares are issued upon the exercise of options or the underwriters exercise their option to purchase additional shares, you will incur further dilution. For a further description of the dilution you will experience immediately after this offering, see “Dilution.”

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease

to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After this offering, we will have shares of common stock outstanding, or shares if the underwriters exercise their option to purchase additional shares in full, in each case based on the shares of our common stock outstanding as of March 31, 2021. Of these shares, the shares (or shares if the underwriters exercise their option to purchase additional shares in full) we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders will continue to have substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

After this offering, our directors and executive officers and their affiliates will beneficially own shares representing approximately % of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock in the foreseeable future. See "Dividend Policy" for additional information.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may remain an emerging growth company until December 31, 2026. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective prior to the closing of this offering, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and bylaws, which will become effective prior to the closing of this offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation will designate the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, which will become effective prior to the closing of this offering, will provide that, subject to limited exceptions, the state or federal courts (as appropriate) within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) action against us or any of our directors or officers involving a claim or defense arising pursuant to the Exchange Act or the Securities Act, or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in "Use of Proceeds." Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

General Risks

A variety of risks associated with operating internationally could materially adversely affect our business.

Our business strategy includes potentially expanding internationally. Doing business internationally involves several risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, economic sanctions laws and regulations, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses, including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, its books and records provisions, or its anti-bribery provisions, as well as other applicable laws and regulations prohibiting bribery and corruption.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

U.S. federal income tax reform could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review through the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and significantly reformed the Code. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. Additionally, on March 27, 2020, President Trump signed into law the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. There also may be technical corrections legislation or other legislative changes proposed with respect to the TCJA and CARES Act, the effects of which cannot be predicted and may be adverse to us or our stockholders. Future changes in tax laws could have a material adverse effect on our business, cash flows, financial condition or results of operations. In particular, the recent presidential and congressional elections in the United States could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Potential clinical trial or product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of any product candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of clinical trial and product liability claims. Clinical trial or product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or

otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, clinical trial or product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The clinical trial and product liability insurance we currently carry, and any additional clinical trial and product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful clinical trial or product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any product candidates we develop.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the significant volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying

interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the timing of our planned IND and CTA submissions for RLYB212 and RLYB116, respectively;
- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials for RLYB211, RLYB212, and RLYB116, and the natural history study for our FNAIT prevention program, and related preparatory work, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates, including RLYB212, RLYB116 and RLYB114;
- the timing of our planned nomination of a compound for our ENPP1 program under our joint venture with Exscientia;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including PNH and gMG;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- the size and growth potential of the markets for RLYB212, RLYB116, RLYB114 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- our ability to expand our pipeline through collaborations, partnerships and other transactions with third parties;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds to us from this offering;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

- our financial performance;
- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

The forward-looking statements in this prospectus are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming no change in the assumed initial public offering price per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of March 31, 2021, we had cash and cash equivalents of $ million. The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and to facilitate our access to the public equity markets.

We intend to use the net proceeds from this offering, together with our cash on hand, as follows:

- Approximately $ million to advance our FNAIT prevention program, including completion of our Phase 1/2 clinical trial for RLYB211 and completion of our Phase 1 and Phase 1b clinical trials for RLYB212;
- Approximately $ million to advance our complement program, including completion of our Phase 1a clinical trial and initiation of our Phase 1b clinical trial for RLYB116 and initiation of our Phase 1 clinical trial for RLYB114;
- Approximately $ million to advance our joint ventures with Exscientia, including the initiation of our Phase 1 clinical trial for our ENPP1 inhibitor; and
- Any remaining proceeds for business development activities and other general corporate purposes.

We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical development efforts, our operating costs and other factors described under “Risk Factors” in this prospectus.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements for more than from the date of this prospectus. This estimate and our expectation regarding the sufficiency of the net proceeds from this offering to advance the preclinical and clinical development of RLYB212, RLYB116 and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We do not anticipate that the expected net proceeds from this offering, together with our existing cash, will be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates, if approved. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never made any cash distributions to our members. Subsequent to our Reorganization, we do not anticipate paying any dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

THE REORGANIZATION

LLC Entity (Rallybio Holdings, LLC)

Currently, the capital structure of Rallybio Holdings, LLC, or the LLC Entity, consists of four classes of membership units: common units; Series A-1 preferred units; Series A-2 preferred units; and Series B preferred units. The LLC Entity is the direct parent company of five subsidiaries: Rallybio, LLC, Rallybio IPA, LLC, Rallybio IPB, LLC, IPC Research, LLC and Rallybio IPD, LLC. Except for Rallybio IPD, LLC, which will become the parent of the other subsidiaries as a result of the Reorganization, the subsidiaries of the LLC Entity focus on developing, identifying, acquiring, and, if approved, commercializing our product candidates, as well as developing and holding intellectual property. Rallybio IPB, LLC jointly owns the joint venture entities with Exscientia.

Reorganization

Prior to the completion of this offering, we intend to complete a series of transactions pursuant to which (i) Rallybio IPD, LLC will be converted from a Delaware limited liability company to a Delaware corporation and change its name to Rallybio Corporation, or the Corporation, (ii) the Corporation will form four direct subsidiaries, each a Delaware limited liability company, or collectively the Merger Subs, (iii) each of the Merger Subs will consummate a separate merger with one of the LLC Entity's direct subsidiaries, other than Rallybio IPD, LLC, or collectively the Asset Subsidiaries, with the Asset Subsidiaries surviving the mergers and the LLC Entity receiving common stock of the Corporation in exchange for its interest in each Asset Subsidiary, which will result in the Asset Subsidiaries becoming subsidiaries of the Corporation and the Corporation becoming the only direct subsidiary of the LLC Entity, and (iv) following this series of mergers, the LLC Entity will liquidate and distribute 100% of the capital stock of the Corporation, consisting solely of common stock, to the unitholders of the LLC Entity. As a result of the Reorganization, the unitholders of the LLC Entity will become the holders of common stock of the Corporation, and the Corporation will become the registrant for purposes of this offering, and our combined and consolidated financial statements will be reported from the Corporation.

As a result of the Reorganization, the unitholders of the LLC Entity will receive 100% of the common stock of the Corporation outstanding as of immediately prior to the completion of the offering. The common stock of the Corporation will be allocated to the holders of existing units in the LLC Entity as follows:

- holders of Series A-1 preferred units and Series A-2 preferred units of the LLC Entity will receive an aggregate of shares of common stock of the Corporation;
- holders of Series B preferred units of the LLC Entity will receive an aggregate of shares of common stock of the Corporation;
- holders of common units of the LLC Entity will receive an aggregate of shares of common stock of the Corporation (including shares of restricted common stock, which will continue to be subject to vesting in accordance with the vesting schedule applicable to such restricted common units); and
- holders of incentive units in the LLC Entity will receive a number of shares of common stock of the Corporation in respect of each incentive unit based upon a conversion price to be determined by our board of directors immediately prior to the Reorganization. Shares of common stock issued in respect of unvested incentive units will be shares of restricted common stock and will continue to be subject to vesting in accordance with the vesting schedule applicable to such incentive units.

The number of shares of common stock that holders of incentive units will receive in the Reorganization will be based on the fair value per common unit, as determined by our board of managers, immediately prior to the Reorganization. In this prospectus, we have assumed a fair value of $ per common unit, which is the midpoint of the price range per share set forth on the cover page of this prospectus. Based on an assumed fair value of $ per common unit, the incentive units will convert into an aggregate of shares of our common stock. At a fair value of $ per common unit, which is the high end of the price range per share set forth on the cover page of this prospectus, the incentive units would convert into an aggregate of shares of our common stock. At a fair value of $ per common unit, which is the low end of the price range set forth on the cover page of this prospectus, the incentive units would convert into an aggregate of shares of our common stock.

As a result of the Reorganization, based on an assumed fair value of $ per common unit, which is the midpoint of the price range per share set forth on the cover page of this prospectus, the holders of existing units in the LLC Entity will collectively own an aggregate of shares of common stock of the Corporation as of immediately prior to the consummation of this offering.

Holding Company Structure

Following the consummation of the Reorganization, the Corporation will be a holding company and the direct parent of: Rallybio, LLC, Rallybio IPA, LLC, Rallybio IPB, LLC and IPC Research, LLC. Except as disclosed in this prospectus, the audited consolidated financial statements for the years ended December 31, 2020 and 2019 and the notes thereto, and selected historical consolidated financial data and other financial information included in this prospectus are those of the LLC Entity and do not give effect to the Reorganization.

On the effective date of the Reorganization, the members of the board of managers of the LLC Entity will become the members of the Corporation's board of directors and the officers of the LLC Entity will become the officers of the Corporation.

The purpose of the Reorganization is to reorganize our corporate structure so that the entity that is offering common stock to the public in this offering is a corporation rather than a limited liability company, and so that our existing investors will own our common stock rather than units in a limited liability company.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis, to give effect to (i) the Reorganization, including the issuance by Rallybio Corporation of an aggregate of shares of its common stock and the subsequent distribution of those shares to members of Rallybio Holdings, LLC, prior to the completion of this offering, as if the Reorganization had occurred as of March 31, 2021, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and (ii) the filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws; and
- on a pro forma as adjusted basis, to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses.

The pro forma as adjusted information below is illustrative only and our capitalization following the closing of this offering will change based on the initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with the financial statements and related notes as appearing at the end of this prospectus and the information set forth under the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	MARCH 31, 2021		
(in thousands, except share and per share amounts)	**ACTUAL**	**PRO FORMA**	**PRO FORMA AS ADJUSTED**
Cash and cash equivalents			
Redeemable preferred units:			
Members’ equity (deficit):			
Redeemable convertible preferred units , no par value; shares authorized, issued or outstanding, actual; shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Common units, no par value; units authorized, issued and outstanding, actual; units authorized, issued and outstanding, pro forma and pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total members’ (deficit), actual; total unitholders’ equity, pro forma and pro forma as adjusted			
Total capitalization			

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders’ deficit and total capitalization on a pro forma as adjusted basis by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders’ deficit and total capitalization on a pro forma as adjusted basis by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

The outstanding share information in the table above as of March 31, 2021 excludes:

- shares of our common stock reserved for issuance under the Rallybio Corporation 2021 Equity Incentive Plan, or the 2021 Plan, which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under the Rallybio Corporation 2021 Employee Stock Purchase Plan, or the ESPP, which will become effective in connection with this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) and historical net tangible book value (deficit) per share have not been presented as there were no common shares outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021 was $ million or $ per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our liabilities, after giving effect to (i) the Reorganization, including the issuance by Rallybio Corporation of an aggregate of shares of its common stock and the subsequent distribution of those shares to members of Rallybio Holdings, LLC, prior to the completion of this offering, as if the Reorganization had occurred as of March 31, 2021, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and (ii) the filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws . Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021 after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and an immediate dilution of $ in pro forma as adjusted net tangible book value per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Pro forma net tangible book value per share of common stock as of March 31, 2021	$	
Increase in net tangible book value per share of common stock attributable to this offering	$	
Pro forma as adjusted net tangible book value per share of common stock after this offering		$
Dilution per share of common stock to new investors participating in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial price to the public of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value by approximately $ million, or approximately $ per share, and increase (decrease) the dilution per share to investors participating in this offering by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value by approximately $ million, or approximately $ per share, and the dilution per share to new investors participating in this offering would be approximately $ per share, assuming that the assumed initial price to the public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value by approximately $ million, or approximately $ per share, and the dilution per share

to investors participating in this offering would be approximately $ per share, assuming that the assumed initial price to the public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase additional shares of common stock from us in this offering, our pro forma as adjusted net tangible book value per share after the offering would be approximately $, representing an immediate increase in pro forma as adjusted net tangible book value per share of approximately $ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of approximately $ to new investors purchasing common stock in this offering, assuming an initial public offering price of approximately $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of March 31, 2021, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration and the average price per share (1) paid by existing stockholders and (2) to be paid by new investors participating in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing stockholders		%		%	
New investors		%		%	
Total		100%		100%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of common stock held by existing stockholders would be reduced to % of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to % of the total number of shares of our common stock to be outstanding upon completion of the offering.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) total consideration paid by new investors by approximately $ million, assuming no change in the assumed initial public offering price.

The share information presented in the tables and discussions above as of March 31, 2021 excludes:

- shares of our common stock reserved for issuance under the 2021 Plan, which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under the ESPP, which will become effective in connection with this offering.

New investors will experience further dilution when any new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities for lower consideration per share than in this offering in the future. In addition, we may choose to raise additional

capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this prospectus and our financial statements and the related notes included elsewhere in this prospectus. The statements of operations and comprehensive loss data for the years ended December 31, 2020 and 2019 and the balance sheet data as of December 31, 2020 and 2019 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations and comprehensive loss data for the three months ended March 31, 2021 and 2020 and our balance sheet as of March 31, 2021 have been derived from our unaudited financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

	YEAR ENDED DECEMBER 31,		THREE MONTHS ENDED MARCH 31,	
(in thousands, except share and per share amounts)	**2020**	**2019**	**2021**	**2020**
Statement of Operations and Comprehensive Loss Data:				
Operating expenses:				
Research and development	$ 17,630	$ 11,366		
General and administrative	7,673	6,276		
Total operating expenses	25,303	17,642		
Loss from operations	(25,303)	(17,642)		
Other income (expense):				
Interest income	171	197		
Interest expense	(49)	(39)		
Other income	241	167		
Change in fair value of Series A-2 financing right obligation	—	(143)		
Total other income, net	363	182		
Loss before income taxes	(24,940)	(17,460)		
Income tax benefit	(15)	—		
Loss on investment in joint venture	1,522	103		
Net loss and comprehensive loss	$ (26,447)	$ (17,563)		
Net loss per common unit, basic and diluted (1)	$ (9.95)	$ (10.24)		
Weighted average common units outstanding—basic and diluted (1)	2,659,187	1,715,164		
Pro forma net loss per share, basic and diluted (1)	$			
Pro forma weighted average common stock outstanding, basic and diluted (1)				

(1) See Note 11 to our financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(in thousands)	DECEMBER 31 2020	2019	MARCH 31, 2021
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$140,233	$ 19,458	
Working capital (1)	135,418	17,114	
Total assets	141,858	21,607	
Total liabilities	5,855	4,747	
Redeemable convertible preferred units	182,027	37,141	
Accumulated deficit	(47,014)	(20,567)	
Total members' (deficit)	$ (46,024)	$(20,281)	

(1) We define working capital as current assets, less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Financial Data" section of this prospectus and our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing and delivering therapies that meaningfully improve the lives of patients suffering from severe and rare diseases. Our mission at Rallybio is aligned with our expertise, and we believe we have assembled the best people, partners and science to forge new paths to life-changing therapies. Since our launch in January 2018, we have acquired a portfolio of promising product candidates that consists of five programs, and we are focused on further expanding our portfolio with the goal of making a profound impact on the lives of even more patients. We are drawing on our decades of knowledge and experience with a determination to tackle the undone, the too difficult, the inaccessible – and change the odds for rare disease patients.

Our most advanced program is for the prevention of fetal and neonatal alloimmune thrombocytopenia, or FNAIT, a potentially life-threatening rare hematological disease that impacts fetuses and newborns. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. We plan to move this program forward with our lead product candidate, RLYB212, a monoclonal anti-HPA-1a antibody, and submit an Investigational New Drug application, or IND, for RLYB212 in . We are also focused on developing therapies that address diseases of complement dysregulation, including paroxysmal nocturnal hemoglobinuria, or PNH, generalized myasthenia gravis, or gMG, and ophthalmic disorders. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with PNH and gMG. We expect to submit a clinical trial application, or CTA, for RLYB116 in . RLYB114 is a pegylated C5 inhibitor in preclinical development for the treatment of complement-mediated ophthalmic diseases and we expect to submit a CTA for this product candidate in . Additionally, in collaboration with Exscientia Limited, or Exscientia, we have two discovery-stage programs focused on the identification of small molecule therapeutics for patients with rare metabolic diseases.

Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates, preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our five programs and our Phase 1/2 clinical trial for RLYB211. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since our inception, we have funded our operations primarily through equity financings and have received proceeds of approximately $182.0 million, net of issuance costs of $0.5 million, from the sale of our preferred units.

To date, we have devoted most of our financial resources to research and development, including our preclinical development and manufacturing activities for each of our five programs and our Phase 1/2 clinical trial for RLYB211. We have not commercialized any products and have never generated revenue from the commercialization of any product.

We have incurred significant operating losses since inception, including net losses of $26.4 million and $17.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had

an accumulated deficit of $47.0 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to incur significant additional operating losses in the foreseeable future as we advance our programs through preclinical and clinical development, expand our research and development activities, acquire and develop new product candidates, complete preclinical studies and clinical trials, finance our business development strategy, seek regulatory approval for the commercialization of our product candidates and commercialize our products, if approved. Our expenses will increase substantially if and as we:

- file an IND and initiate a Phase 1 clinical trial for RLYB212, our lead product candidate for our FNAIT prevention program;
- file an IND or a CTA and initiate our clinical trials for RLYB116 and other product candidates;
- initiate a natural history alloimmunization study of FNAIT to support our development program and related regulatory submissions for RLYB212;
- continue to develop and conduct clinical trials with respect to RLYB211;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- continue and expand upon our discovery and development joint ventures with Exscientia;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- add operational, financial, and management personnel, including personnel to support our product development and planned future commercialization efforts and to support our transition to a public company;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any product candidate for which we obtain regulatory approval; and
- establish a sales, marketing and distribution infrastructure to commercialize our programs, if approved, and for any other product candidates for which we may obtain marketing approval.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

As of December 31, 2020, we had cash and cash equivalents of $140.2 million. We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for more than from the date of this prospectus. This estimate and our expectation regarding the sufficiency of the net proceeds from this offering to advance the preclinical and clinical development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources.”

Impact of COVID-19

The COVID-19 pandemic has impacted and may continue to impact our preclinical studies and clinical trials, including at our clinical sites and the startup activities for our clinical trials, as well as our manufacturing and supply chain, and the pandemic may affect our ability to timely complete our clinical trials and delay the initiation and/or enrollment of any future clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations.

We are monitoring the potential impact of the COVID-19 pandemic on our business and financial statements. To date, we have not incurred impairment losses in the carrying values of our assets as a result of the COVID-19 pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our financial statements. We plan to continue many of the protective measures we

implemented in response to the pandemic and are assessing when and how to resume normal operations for office-based personnel. The effects of the public health directives and our work-from-home policies may disrupt our business and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, results of operations and financial condition, including our ability to obtain financing.

We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, including the availability and administration of vaccines, and the duration and intensity of the related effects.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research and development activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under agreements with third parties, such as contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including fees paid to CMOs;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- employee-related expenses, including salaries, bonuses, benefits, equity-based compensation and other related costs for those employees involved in research and development efforts;
- costs of outside consultants, including their fees, and related travel expenses;
- the costs of acquiring and developing clinical trial materials;
- expenses to acquire technologies, such as intellectual property, to be used in research and development including in-process research and development, or IPR&D, that has no alternative future use at the time of asset acquisitions;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other indirect costs.

Costs for certain activities are recognized based on an evaluation of the progress to completion of each specific contract using information and data provided to us by our vendors and analyzing the progress of our research studies or other services performed. Significant judgments and estimates are made in determining the expenses incurred balances at the end of any reporting period.

Our direct, external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. We track these external research and development costs on a program-by-program basis.

We do not allocate employee costs, costs associated with our development efforts and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and development activities as well as for managing our process development, manufacturing and clinical development activities.

The successful development of our product candidates is highly uncertain. We plan to substantially increase our research and development expenses in the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly with our ongoing clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. For example, if the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

We anticipate that our research and development expenses will continue to increase as we continue our current research programs, initiate new research programs, continue our preclinical development of product candidates and conduct future clinical trials for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and equity-based compensation for our personnel in executive, legal, business development, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, tax and consulting services, insurance costs, travel expenses and direct and allocated facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase as we increase headcount that provide administrative support to our research and development activities. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Total Other Income, Net

Total other income, net, includes interest income earned on cash and cash equivalents, interest expense and other income and expense items including the change in fair value of financing right obligations related to our Series A-2 financing.

Loss on investment in joint venture

The Company recognizes its pro-rata share of losses in the loss on investment in joint venture with Exscientia on its consolidated statements of operations and comprehensive loss, with a corresponding change to the investment in joint venture on the consolidated balance sheets for equity method investments for which it does not have a controlling interest in.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations:

(in thousands)	YEAR ENDED DECEMBER 31, 2020	2019	CHANGE
Operating expenses:			
Research and development	$ 17,630	$ 11,366	$ 6,264
General and administrative	7,673	6,276	1,397
Total operating expenses	25,303	17,642	7,661
Loss from operations	(25,303)	(17,642)	(7,661)
Total other income, net:	363	182	181
Income tax benefit	(15)	—	(15)
Loss on investment in joint venture	1,522	103	1,419
Net loss	$ (26,447)	$ (17,563)	$ (8,884)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented:

(in thousands)	YEAR ENDED DECEMBER 31, 2020	2019	CHANGE
Direct research and development by program			
RLYB211	$ 4,099	$ 3,189	$ 910
RLYB212	3,686	202	3,484
RLYB116	5,842	700	5,142
Other program candidates	50	22	28
Asset acquisitions IPR&D expense	—	6,113	(6,113)
Other unallocated research and development costs			
Personnel expenses (including equity-based compensation)	3,883	1,140	2,743
Other expenses	70	—	70
Total research and development expenses	$ 17,630	$ 11,366	$ 6,264

Research and development expenses were $17.6 million for the year ended December 31, 2020, compared to $11.4 million for the year ended December 31, 2019. The increase of $6.3 million was primarily due to:

- a $3.5 million increase in costs related to the development of RLYB212 and a $5.1 million increase in costs related to the development of RLYB116 mainly attributable to increased external manufacturing activities for both programs as compared to the same period in 2019 when the assets were acquired;
- a $2.8 million increase in personnel-related costs, including equity-based compensation expense, primarily due to an increase in research and development related headcount as compared to the same period in 2019;
- a $0.9 million increase in RLYB211 related to an increase in clinical development costs as compared to the same period in 2019; and
- a decrease of $6.1 million in asset acquisition related IPR&D expenses related to the asset acquisitions made in 2019. No asset acquisitions were executed in 2020.

General and Administrative Expenses

General and administrative expenses were $7.7 million for the year ended December 31, 2020, compared to $6.3 million for the year ended December 31, 2019. The increase of $1.4 million primarily related to an increase in payroll and personnel-related costs, including equity-based compensation, primarily due to an increase in general and administrative related headcount and other professional fees associated with operating activities and the preparations for becoming a public company.

Total Other Income, Net

Total other income, net, was $0.4 million for the year ended December 31, 2020, compared to $0.2 million for the year ended December 31, 2019. The increase of $0.2 million is primarily attributable to the change in fair value of our Series A-2 financing right obligation expense for the year ended 2019, no such charges for financing obligation rights were taken for the same period in 2020.

Loss on investment in joint venture

For the year ended December 31, 2020, the loss recognized was $1.5 million as compared to $0.1 million for the same period in 2019. The joint venture with Exscientia was established in July 2019 and the increase in the loss recognized is due to increases in research and development cost recognized by the underlying joint venture during 2020 as compared to 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through equity financings, and through December 31, 2020, had received proceeds of approximately $182.0 million, net of issuance costs of $0.5 million, from the sale of our preferred units. As of December 31, 2020, we had $140.2 million of cash and cash equivalents.

Uses of Liquidity

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our manufacturing, licensing and lease obligations described further below.

Funding Requirements

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements for more than from the date of this prospectus. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect to incur significant expenses and operating losses in the foreseeable future as we advance our product candidates through clinical development, seek regulatory approval and pursue commercialization of any approved product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the actual

amount of funds we will require for development, approval and any approved marketing and commercialization activities. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including our ongoing Phase 1/2 clinical trial for RLYB211, the planned clinical trials for RLYB212 and RLYB116 and the development of any other product candidates;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities, including any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for RLYB212 or any other product candidates, including design, manufacturing and regulatory approval;
- the cost of filing, prosecuting and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- our ability to develop and commercialize products that are considered medically and/or financially differentiated to competitive products by physicians, patients and payers;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of making royalty, milestone or other payments under any future in-license agreements;
- our ability to maintain our collaboration with Exscientia on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies;
- the severity, duration and impact of the COVID-19 pandemic, which may adversely impact our business;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- the initiation, progress and timing of our commercialization of RLYB212, RLYB116, if approved, or any other product candidates;
- the availability of third-party coverage and reimbursement for and pricing of any approved products; and
- the costs of operating as a public company.

A change in the outcome of any of these, or other variables with respect to the development of any of our product candidates, could significantly change the costs and timing associated with the development of that product candidate. We will need to continue to rely on additional financing to achieve our business objectives.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We currently have no credit facility or committed sources of capital. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting

our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	YEAR ENDED DECEMBER 31,	
	2020	2019
(in thousands)		
Net cash used in operating activities	$ (22,039)	$ (15,026)
Net cash used in investing activities	(2,072)	(188)
Net cash provided by financing activities	144,886	31,567
Net increase in cash and cash equivalents	$ 120,775	$ 16,353

Operating Activities

Net cash used in operating activities was $22.0 million for the year ended December 31, 2020 as compared to $15.0 million in 2019. The increase in cash used in operations was primarily due to the increase of $6.3 million in research and development and $1.4 million in general and administrative expenses for the increased efforts advancing the development of RLYB211, RLYB212 and RLYB116 product candidates as compared to the same period the prior year.

Investing Activities

Net cash used in investing activities was $2.1 million for the year ended December 31, 2020 as compared to $0.2 million in 2019. The increase in net cash used in investing activities was primarily related to the investments in our joint venture as compared to the same period the prior year.

Financing Activities

Net cash provided by financing activities was $144.9 million for the year ended December 31, 2020 as compared to $31.6 million in 2019. The increase in financing activities was primarily attributable to the net proceeds from the issuance of Series B Preferred units of $144.9 million as compared to the net proceeds from the issuance of Series A-2 Preferred units of $31.6 million from the prior year.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020:

	PAYMENTS DUE BY PERIOD				
(in thousands)	**TOTAL**	**LESS THAN 1 YEAR**	**1-3 YEARS**	**3-5 YEARS**	**MORE THAN 5 YEARS**
Operating lease obligations	$ 507	$ 83	$ 221	$ 203	$ —

The contractual obligation amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions and the approximate timing of the actions under the contracts.

Purchase and Other Obligations

We enter contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services. Aside from those included in the table above, most contracts do not contain

minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consist of payments for services provided or expenses incurred. These payments are not included in the table above as the amount and timing of such payments are not known.

We may incur contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable under agreements we have entered into with various third-party entities pursuant to which we have acquired or in-licensed intellectual property. Due to the uncertainty of the achievement and timing of the events that require payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time and have not been included in the table above. See “Business—License Agreement” and “Business—Asset Purchase Agreements” and Note 3 “Asset Acquisitions” to our audited consolidated financial statements included elsewhere in this prospectus for a description of these agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States or U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 “Summary of Significant Accounting Policies and Basis of Presentation and Principles of Consolidation” to our audited consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses that are incurred as of each reporting period. This process involves reviewing open contracts and purchase orders, communicating with our personnel and with vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Incentive Units

Prior to this offering, we have periodically granted incentive units to employees which vest over a four-year period. These incentive units have been issued in the form of profits interests providing the employee with compensation equal to the increase in the value of the unit over a participation threshold per unit, as determined at the time of grant. The holder, therefore, has the right to participate in distributions of profits only in excess of such participation threshold. The participation threshold is based on the valuation of a single common unit on the grant date.

We measure equity-based compensation based on the grant date fair value of the unit-based awards and recognize equity-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. Unit-based compensation expense is classified in our consolidated statements of operations and comprehensive loss based on the function to which the related services are provided or in the same manner in which the grantee's payroll costs are classified. Forfeitures are accounted for as they occur.

As there has been no public market for our common units, the estimated fair value of our common units has been determined by our board of managers after considering valuation reports provided by an independent third-party valuation firm. In accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, a third-party valuation firm prepared valuations of our common units using an option pricing method, or OPM, which uses market approaches, and a Black-Scholes option pricing model to estimate our enterprise value. The OPM treats common units and preferred units as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes to value the common units of the company. A discount for lack of marketability of the common units is then applied to arrive at an indication of value for the common units as of the valuation date.

There are significant judgments related to volatility and time to liquidity as well as estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our product candidates, the timing of a potential IPO or other liquidity events and the determination of the appropriate valuation methodology at each valuation date. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation expense could be materially different. Following the completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

In connection with the Reorganization, holders of common and incentive units of Rallybio Holdings, LLC, or the LLC Entity, will receive shares of common stock and restricted stock of Rallybio Corporation, or the Corporation, based upon a conversion price to be determined by our board of directors immediately prior to the Reorganization. Holders of incentive units of the LLC Entity that are vested as of the consummation of the Reorganization will, with respect to such units, receive shares of common stock of the Corporation. Holders of incentive units of the LLC Entity that are unvested as of the consummation of the Reorganization will, with respect to such units, receive shares of restricted stock of the Corporation. The shares of restricted common stock will be subject to the same vesting conditions as the incentive units for which such shares are exchanged. The following table summarizes by grant date the number of incentive units granted from January 5, 2018 through December 31, 2020, the participation threshold price per incentive unit and the pro forma number of shares of common stock that will be issued in the Reorganization for each grant of incentive units:

GRANT DATE	INCENTIVE UNITS GRANTED	OUTSTANDING INCENTIVE UNITS AS OF DECEMBER 31, 2020	PARTICIPATION THRESHOLD PRICE PER UNIT	PRO FORMA COMMON STOCK ISSUED IN RESPECT OF INCENTIVE UNITS
July 2018 – January 2019	285,000	285,000	0.10	
July 2019 – December 2019	1,348,000	1,348,000	0.42	
May 2020 – December 2020	5,232,704	5,232,704	0.44	

Emerging Growth Company and Smaller Reporting Company

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

We may remain classified as an EGC until the end of the fiscal year in which the fifth anniversary of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we will cease to be an EGC as of December 31 of the applicable year. We also will cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an EGC, we are not required to, among other things, provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 "Summary of Significant Accounting Policies and Basis of Presentation and Principles of Consolidation" to our consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a clinical-stage biotechnology company built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing and delivering therapies that meaningfully improve the lives of patients suffering from severe and rare diseases. Our mission at Rallybio is aligned with our expertise, and we believe we have assembled the best people, partners and science to forge new paths to life-changing therapies. Since our launch in January 2018, we have acquired a portfolio of promising product candidates that consists of five programs, and we are focused on further expanding our portfolio with the goal of making a profound impact on the lives of even more patients. We are drawing on our decades of knowledge and experience with a determination to tackle the undone, the too difficult, the inaccessible – and change the odds for rare disease patients.

Our most advanced program is for the prevention of fetal and neonatal alloimmune thrombocytopenia, or FNAIT, a potentially life-threatening rare hematological disease that impacts fetuses and newborns. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. We plan to move this program forward with our lead product candidate, RLYB212, a monoclonal anti-HPA-1a, antibody and submit an Investigational New Drug application, or IND, for RLYB212 in . We are also focused on developing therapies that address diseases of complement dysregulation, including paroxysmal nocturnal hemoglobinuria, or PNH, generalized myasthenia gravis, or gMG, and ophthalmic disorders. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with PNH and gMG. We expect to submit a clinical trial application, or CTA, for RLYB116 in . RLYB114 is a pegylated C5 inhibitor in preclinical development for the treatment of complement-mediated ophthalmic diseases and we expect to submit a CTA for this product candidate in . Additionally, in collaboration with Exscientia Limited, or Exscientia, we have two discovery-stage programs focused on the identification of small molecule therapeutics for patients with rare metabolic diseases.

Our Approach

At Rallybio, we do not accept that millions of patients suffering from devastating rare diseases should have to live without transformative treatments. There are an estimated 25 to 30 million people affected by as many as 7,000 rare diseases in the United States alone, with a significantly greater number of affected people globally. We are building a diversified pipeline of product candidates that we believe have the potential to transform the lives of patients in need. Our goal is to deliver therapeutics that provide meaningful clinical benefits to patients so they can become unbound and undefined by the diseases from which they suffer.

We believe the success of our company is built on three key strengths:

- **Our extensive knowledge of rare diseases and our scientific expertise positions us to identify therapies with the potential for transformative impact.** We seek to acquire and develop product candidates that possess a clear mechanism of action and that aim to address diseases with a well-understood pathophysiology for which there is a significant unmet medical need. We believe that a product candidate's mechanism of action should target the causal biology of the disease to provide the highest probability of dramatically improving the lives of patients. We believe that our team's extensive experience in rare diseases and our scientific expertise position us to identify opportunities where these links can be made, which may go unnoticed by others.
- **Our ability to source, to identify and to evaluate potential high-quality product candidates**. We apply decades of experience across drug discovery, research, development, regulatory strategy and manufacturing to source, to identify and to evaluate therapeutic targets and product candidates that we believe have a high probability of success. Our ability to source these product candidates is facilitated by our extensive network of relationships with leaders in industry and in academic clinical centers worldwide. We view ourselves as partners of choice given our team's track record of success in developing and delivering new therapies to patients.

- **Our team's proven execution capability to drive product candidates through clinical development to regulatory approvals.** We have assembled a team with a proven history of successfully advancing product candidates from discovery to clinical development and through regulatory approval. Members of our team have played critical roles in the approval of more than 30 drugs and secured approvals from regulatory authorities in the Americas, Europe and Asia. In doing so, our employees previously developed and implemented novel clinical trial designs and successfully conducted clinical trials in never-before treated patient populations. We believe this collective prior experience positions us to efficiently and expertly execute at each step in the research and development process and enhances the value we can bring to product candidates and to patients.

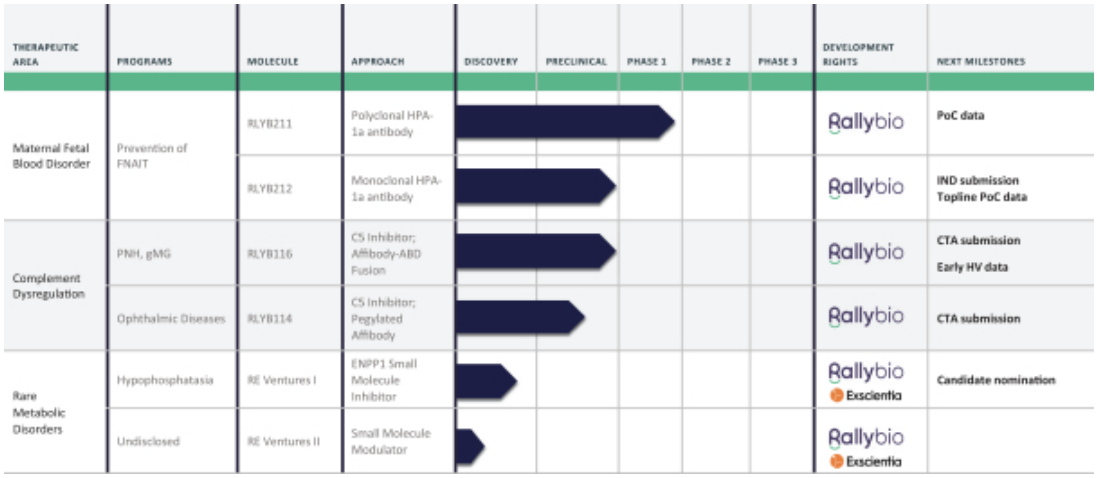
Our Team

Our founders, Martin W. Mackay, Ph.D., Stephen Uden, M.D., and Jeffrey M. Fryer, CPA, were previously executives at Alexion Pharmaceuticals, Inc., or Alexion, and worked together to successfully build, develop, and launch transformative therapies for patients with rare diseases. Several members of our team were integral in the successful development and/or approval of therapies such as Strensiq (asfotase alfa) for patients with perinatal-, infantile-, and juvenile-onset hypophosphatasia, or HPP, Kanuma (sebelipase alfa) for patients with lysosomal acid lipase deficiency, or LAL-D, Nulibry (fosdenopterin) for patients with molybdenum cofactor deficiency, or MoCD Type A, Soliris (eculizumab) for patients with refractory gMG, Soliris for patients with relapsing neuromyelitis optica spectrum disorder, or NMOSD, Ultomiris (ravulizumab-cwvz), for patients with PNH and Ultomiris for patients with atypical hemolytic uremic syndrome, or aHUS.

Our deep commitment to high ethical and professional standards is fundamental to our mission to bring new and transformative medicines to vulnerable patient populations suffering from rare diseases. We believe our team's prior contributions have made a significant positive impact on the lives of thousands of patients around the world. As a strong and experienced team, we believe we can transform the lives of thousands more.

Our Pipeline

Our pipeline is illustrated in the chart below.



FNAIT: Fetal and neonatal alloimmune thrombocytopenia; HPA-1a: Human platelet antigen 1a; PNH: Paroxysmal nocturnal hemoglobinuria; gMG: Generalized myasthenia gravis; ABD: Albumin-binding domain; ENPP1: Ectonucleotide pyrophosphatase/phosphodiesterase 1; PoC: Proof of concept; IND: Investigational new drug; CTA: Clinical trial application; HV: Healthy volunteer

Prevention of FNAIT

Our most advanced program is targeting the prevention of FNAIT, a potentially life-threatening rare disease that can cause uncontrolled bleeding in fetuses and newborns. FNAIT can arise during pregnancy due to an immune incompatibility between an expectant mother and her fetus in a specific platelet antigen called human platelet

antigen 1, or HPA-1. This incompatibility can cause an expectant mother to develop antibodies that attack the platelets of her fetus. The destruction of platelets in the fetus can result in severely low platelet counts, or thrombocytopenia, potentially leading to devastating consequences including miscarriage, stillbirth, death of the newborn, or severe lifelong neurological disability in those babies who survive. There is currently no approved therapy for the prevention or treatment of FNAIT.

We estimate that there are over 22,000 pregnancies at high risk of developing FNAIT each year in the United States, Canada, United Kingdom, other major European countries and Australia. Because there are no approved therapies to prevent FNAIT, expectant mothers are not currently screened for FNAIT risk. As a result, the vast majority of pregnancies at risk for FNAIT go unidentified and untreated. In those pregnancies that are identified as at-risk, typically due to the delivery of a prior FNAIT affected child, expectant mothers may be treated with weekly intravenously-administered high doses of immunoglobulin G, or IVIG, along with the oral steroid immunosuppressant prednisone. However, IVIG administration does not prevent the immune response, called alloimmunization, and is costly, time-intensive, difficult to tolerate and associated with significant treatment-related complications.

The lead product candidate in our FNAIT prevention program is RLYB212, a preclinical-stage monoclonal anti-HPA-1a antibody. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. RLYB211 is derived from the plasma of women who have developed antibodies to HPA-1a as a result of a prior HPA-1 incompatible pregnancy. Data generated from the first cohort of healthy participants in our Phase 1/2 clinical trial for RLYB211 demonstrated the ability of an anti-HPA-1a antibody to rapidly eliminate transfused HPA-1a positive platelets from the circulation of healthy HPA-1a negative participants. Based on these results, we believe that targeting HPA-1a with an anti-HPA-1a antibody has the potential to prevent maternal alloimmunization and therefore the occurrence of FNAIT.

Based on the common mechanism of action, we believe that both product candidates will drive rapid elimination of HPA-1a positive platelets in the circulation of expectant mothers and potentially prevent them from alloimmunizing. Consequently, we are prioritizing the development of RLYB212 based on its favorable attributes, including:

- the potential for subcutaneous administration of RLYB212, which is the preferred route of administration based on primary market research of OB/GYNs and maternal-fetal specialists in the United States and Europe, compared to RLYB211's intravenous injection administration;
- a pharmacokinetic profile for RLYB212 that has the potential to maintain circulating concentrations of anti-HPA-1a antibody at levels that are very close to peak exposure levels through the entire treatment period, thus maximizing the capacity of RLYB212 to neutralize fetal antigen relative to RLYB211; and
- the ability to produce RLYB212 using standard monoclonal antibody manufacturing methods compared to the long-term need to source plasma for RLYB211 from women who had developed antibodies to HPA-1a as a result of a prior HPA-1 incompatible pregnancy.

We expect to submit an IND for RLYB212 in , and to initiate a Phase 1 clinical trial in healthy participants by . We anticipate reporting additional data from our Phase 1/2 clinical trial for RLYB211 in .

Treatment of Disorders Due to Complement Dysregulation

Our next two programs target diseases related to complement pathway dysregulation. The complement system plays a central role in innate immunity, as well as, shaping adaptive immune response. Dysregulation of the complement pathway has been implicated in the pathogenesis of a growing number of diseases, making it an attractive target for therapeutic intervention.

Antibody inhibitors of C5 have been successfully developed to treat diseases caused by complement pathway dysregulation, including PNH, aHUS, refractory gMG and relapsing NMOSD. Despite the approval of antibody-based C5 inhibitors for patients with these diseases, we believe there remains significant need in the market for safe, effective, patient-friendly and accessible therapies.

Our team has a track record of success and significant expertise in designing, developing and securing approval for complement inhibitors, including Soliris and Ultomiris, for patients with severe and rare complement-mediated

diseases around the world. We believe this knowledge and expertise positions us to successfully advance our programs and deliver transformative benefits to patients in need.

Our most advanced product candidate in this therapeutic area is RLYB116, an inhibitor of complement factor C5, which is a central component of the complement pathway. RLYB116 is an Affibody® molecule attached to an albumin binding domain that has the potential to drive the rapid, complete and sustained inhibition of C5 with a subcutaneous injection. We plan to pursue PNH and gMG as our lead indications for RLYB116. We also plan to evaluate the development of RLYB116 for the treatment of additional rare complement-mediated diseases. We expect to submit a CTA for RLYB116 in , and to initiate a Phase 1 clinical trial by .

Our second C5 inhibitor, RLYB114, is a pegylated C5-targeted Affibody® molecule with pharmacokinetic properties designed for the treatment of complement-mediated ophthalmic diseases. Preclinical data generated with RLYB114 demonstrate that it is well-tolerated in animal models with no serious adverse effects. We expect to submit a CTA for RLYB114 in .

Artificial Intelligence Drug Discovery Collaboration

We have established a partnership with Exscientia, an Oxford, UK-based artificial intelligence-driven pharmatech company that is a leader in the use of computational tools and machine learning capabilities to rapidly and efficiently discover novel small molecule drug candidates. Our partnership consists of two joint ventures that each focus on the discovery and development of small molecule therapeutics for the treatment of patients with rare metabolic diseases.

The first of these programs is targeting Ectonucleotide Pyrophosphatase/ Phosphodiesterase 1, or ENPP1, for the treatment of patients with HPP, a potentially life-threatening disease due to defects of skeletal mineralization. Patients with HPP suffer from deficiencies in breaking down pyrophosphate due to loss of function mutations in the gene ALPL, which encodes Tissue Non-specific Alkaline Phosphatase, or TNSALP. ENPP1 is an enzyme involved in regulating extracellular levels of pyrophosphate, a natural inhibitor of calcium mineralization in bone formation. We believe that a small molecule inhibitor of ENPP1 has the potential to bring meaningful benefit to HPP patients by reducing excess levels of pyrophosphate, thereby removing an inhibitor of calcium mineralization and bone formation.

The incidence of HPP has been reported to be 1 in 100,000 to 1 in 300,000 (United States and Canada) for severe disease and 1 in 6,370 (EU) for less severe forms. In functional in vitro assays, we have observed that our lead ENPP1 inhibitors can promote mineralization. We intend to nominate a compound for clinical development in this program in .

In addition, we have a second joint venture with Exscientia, which is currently in the discovery stage, to identify a small molecule modulator for patients with an undisclosed rare metabolic disorder.

Our Strategy

Our mission at Rallybio is aligned with our expertise: to identify and accelerate the development of life-transforming therapies for patients with severe and rare disorders. To achieve this mission, our strategy includes the following key components:

- **Establish a leading rare disease company through a team that delivers transformative medicines to patients.** We believe our team's expertise and knowledge are fundamental to our long-term success. Our research and development team is led by experienced drug development executives who were integral in the approvals of more than 30 drugs from leading companies, including Alexion, Astellas Pharma Inc., Wyeth, LLC and Pfizer Inc. We plan to continue to leverage our team's expertise to enable focused clinical development of multiple product candidates in parallel, resulting in a diversified portfolio that we believe will provide multiple opportunities to create value by significantly improving the lives of patients.
- **Rapidly advance RLYB212 through clinical development for the prevention of FNAIT.** Our polyclonal antibody, RLYB211, is currently being evaluated in a Phase 1/2 clinical trial. We expect to release topline data from this trial in , which we believe establishes proof of concept for RLYB211 and an anti-HPA-1a antibody approach. We plan to submit an IND for RLYB212 in and to initiate a Phase 1

clinical trial by . To further support our clinical development, we plan to initiate a global natural history study of FNAIT in .

- **Rapidly advance RLYB116 and RLYB114 through clinical development for the treatment of diseases of complement dysregulation.** We intend to submit a CTA for RLYB116 for treatment of PNH and gMG in with the goal of initiating a Phase 1 clinical trial by . We plan to pursue PNH and gMG as our lead indications for RLYB116. We also plan to evaluate the development of RLYB116 for the treatment of additional rare complement-mediated diseases. In addition, we are proceeding with preclinical development of RLYB114 for complement-mediated ophthalmic indications.
- **Identify and advance pipeline product candidates for rare metabolic diseases through our joint ventures with Exscientia.** We have entered into a partnership with Exscientia to identify and develop candidates that are aligned with our overall drug discovery and development strategy. We plan to identify a lead candidate for our ENPP1 program by . We also continue to execute on a second target with Exscientia with the goal of identifying a small molecule modulator for the treatment of an undisclosed rare metabolic disorder and expect to pursue additional small molecule targets in collaboration with Exscientia in additional joint ventures.
- **Expand our pipeline through partnering, acquiring or in-licensing additional product candidates that target validated biology.** We are focused on developing drugs that directly impact known disease pathways which we believe will allow us to increase the probability of clinical, regulatory and commercial success. We continue to accelerate our business development activities and actively pursue the acquisition or in-licensing of additional product candidates as well as partnerships and collaborations. Our team has strong relationships with key academic and industry leaders in the rare disease field built from our past success in developing and commercializing therapies for rare diseases. We plan to continue to leverage these relationships to further our business development opportunities and thereby expand our pipeline.
- **Maximize the value of pipeline product candidates through commercial independence in key markets and select partnerships.** We plan to build a fully integrated and focused commercial organization to launch our rare therapeutics, if approved, in key markets. We believe our commercial organization can be efficiently targeted at groups of specialists who typically treat patients with the diseases to be addressed by our product candidates. For certain other markets, we plan to explore strategic partnerships to efficiently deliver our therapeutics to patients, with the goal of transforming patient care in our focus areas around the globe.

Our Company

We were founded in January 2018 by Drs. Mackay and Uden and Mr. Fryer to identify and accelerate the development of life-transforming therapies for patients with severe and rare disorders. At Alexion, Dr. Mackay was Global Head of Research & Development, Dr. Uden served as Head of Research, and Mr. Fryer was Chief Tax Officer. Many of our employees have worked together extensively during their careers across different companies. During these years of collaboration, several members of our team were integral in the successful development and/or approval of transformative therapies for thousands of patients with rare diseases. As a focused, cohesive and experienced Rallybio team, we hope to transform the lives of many thousands more.

To date, we have raised over $180 million from investors including 5AM Ventures, Canaan Partners, Connecticut Innovations, Fairview Capital, F-Prime Capital, Mitsui & Co. Global Investment, New Leaf Venture Partners, Pivotal bioVenture Partners, Solasta Ventures, Tekla Capital Management, TPG, and Viking Global Investors. In addition, employees of Rallybio have invested over $2.3 million to date in our Series A-1, Series A-2, and Series B financing transactions.

Our Product Candidates

RLYB211 and RLYB212 for the prevention of FNAIT

We are developing two anti-HPA-1a antibody product candidates, RLYB211 and RLYB212, for the prevention of FNAIT, a maternal fetal blood disorder that can cause potentially devastating outcomes including miscarriage, neonatal death and severe life-long neurological disability. RLYB211 is a polyclonal anti-HPA-1a antibody isolated from the plasma of women who developed HPA-1a antibodies due to a prior HPA-1 incompatible pregnancy, and we

believe early data generated from the first cohort of our ongoing Phase 1/2 clinical trial for RLYB211 in healthy male participants supports the potential of our approach to prevent material alloimmunization and therefore the occurrence of FNAIT. RLYB212 is a monoclonal antibody directed at the same HPA-1a target and we intend to advance this product candidate into clinical trials by .

Maternal fetal blood disorders

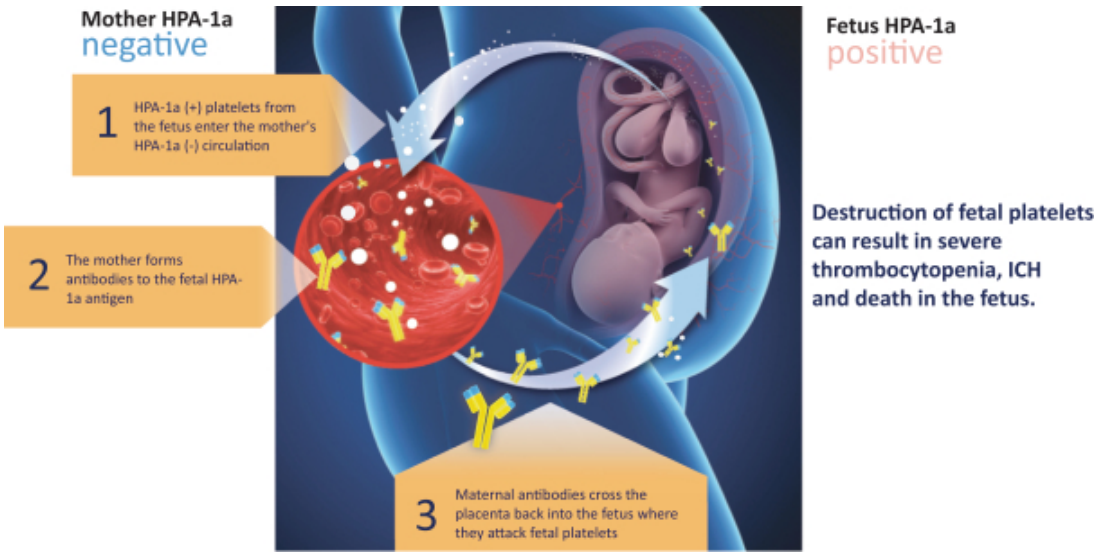
FNAIT is one of several devastating disorders that is caused by an immune incompatibility of a mother and fetus during pregnancy. One of the best-characterized prenatal immune incompatibility disorders is Rh disease. This condition arises when the mother is RhD negative and her fetus is RhD positive. RhD incompatibility may lead to destruction of red blood cells in the fetus and can result in severe outcomes including miscarriage or loss of a newborn. RhD disease is treated by giving at-risk expectant mothers low doses of antibodies to RhD. These antibodies remove fetal red blood cells that have crossed into the mother's circulation, thereby preventing her from developing an immune response that could destroy the red blood cells in the fetus. Since the approval of the first Rho (D) Immune Globulin in 1968, known as RhoGAM, expectant mothers in many countries, including North America and Europe, are routinely screened for their RhD status, and Rh disease is largely prevented in at-risk expectant mothers. We are pursuing a similar approach to preventing FNAIT with our product candidates.

FNAIT disease background

Like Rh disease, FNAIT is a disorder that occurs during pregnancy when an expectant mother's immune system attacks a specific antigen on the platelets of her fetus, leading to their destruction. This results in an increased risk of bleeding in the fetus and newborn. In the majority of cases, the effects of FNAIT are mild; however, up to 20% of FNAIT cases experience intracranial hemorrhage, or ICH, which can lead to devastating outcomes such as miscarriage, stillbirth, loss of the newborn and severe lifelong neurological disabilities in those babies that survive.

FNAIT is caused by a mismatch in the type of human platelet antigen 1, or HPA-1, that is expressed by the expectant mother and the fetus. There are two predominant forms of HPA-1, known as HPA-1a and HPA-1b, which are expressed on the surface of platelets. These two alleles differ by a single amino acid. Individuals who are homozygous for HPA-1b, meaning that they have two copies of the HPA-1b allele and no copies of the HPA-1a allele, are also known as HPA-1a negative. Upon exposure to HPA-1a, these individuals can develop antibodies to that antigen in a process known as alloimmunization. In expectant mothers, alloimmunization can occur upon mixing of fetal blood with maternal blood. When alloimmunization occurs in an expectant mother, the anti-HPA-1a antibodies that develop in the mother can cross the placenta and destroy platelets in the fetus.

Pathophysiology of FNAIT



There are no approved therapies to treat or prevent FNAIT and, therefore, expectant mothers are not currently screened for FNAIT risk. Today, expectant mothers at risk of FNAIT are typically only identified following the delivery of an FNAIT affected child. These mothers may be treated during subsequent pregnancies with weekly administration of IVIG, along with the oral steroid immunosuppressant prednisone. While IVIG administration can potentially mitigate the detrimental effects of anti-HPA-1a antibodies, it does not prevent alloimmunization, and IVIG is costly, time-intensive, difficult to tolerate and associated with significant treatment-related complications.

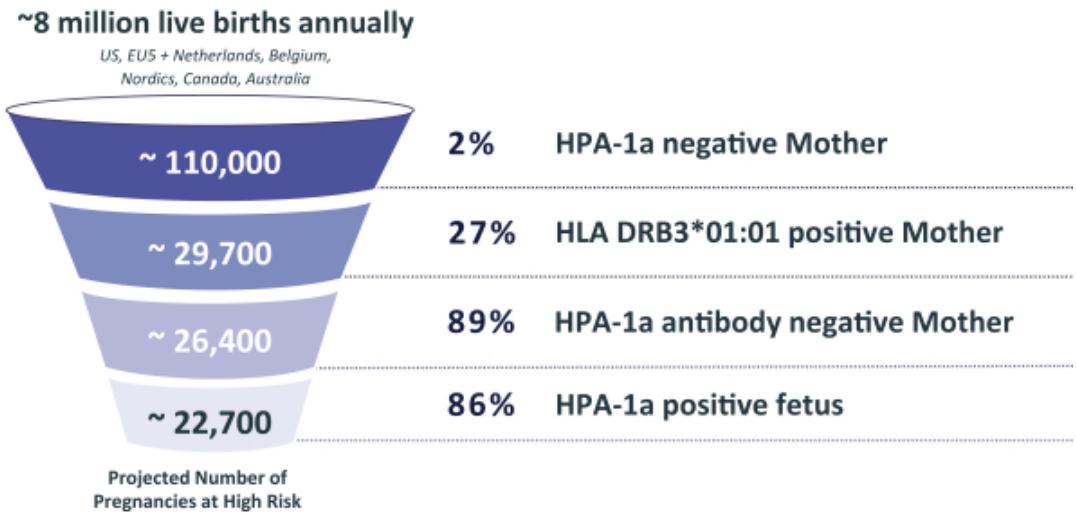
Babies with FNAIT are typically diagnosed at the time of delivery by the presence of low platelet counts identified during routine analysis, the presence of petechiae on the skin or due to the manifestations of severe complications such as ICH or gastrointestinal bleeding. Upon diagnosis, babies with FNAIT may receive platelet transfusions and may be admitted to the neonatal intensive care unit. In severe cases, babies may suffer life-long neurological disability or may not survive.

We project that there may be over 22,000 pregnancies annually that are at high risk of FNAIT in the United States, Canada, United Kingdom, other major European countries and Australia. These pregnancies represent expectant mothers who are HPA-1a negative, who are at high risk of alloimmunization and who are carrying an HPA-1a positive fetus.

While the frequency of HPA-1a negative status in non-Caucasian populations is not established, studies show that approximately 2% of the Caucasian population is HPA-1a negative. Based on this frequency and live birth rates of Caucasian women from 2018, we estimate that there are approximately 110,000 HPA-1a negative expectant mothers in the aforementioned countries each year. From this population of expectant mothers, a subset is at higher risk of FNAIT due to the presence of a specific HLA allele, known as DRB3*01:01. Genetic studies have found that expectant mothers who have this specific HLA allele are approximately 25 times more likely to develop antibodies to HPA-1a than those without this allele. This higher-risk group represents approximately 27% of HPA-1a negative expectant mothers, or approximately 30,000 individuals.

From this population, an estimated 89% of women would not already have antibodies to HPA-1a and, of these, an estimated 86% would be expected to be carrying an HPA-1a positive fetus. As illustrated below, based on these estimates, we project there may be over 22,000 pregnancies annually that are at high risk of FNAIT.

FNAIT Pregnancies At Risk



Given the well-established prevalence of HPA-1a negativity in the Caucasian population, our current estimates of the FNAIT at-risk population are derived from the estimated proportion of Caucasian births from approximately eight million live births per year in the above-mentioned countries. However, we are committed to ensuring that all

expectant mothers of any race or ethnicity who are at high risk of FNAIT are identified and eligible for treatment. We intend to initiate a natural history study of FNAIT in , in part to obtain better prevalence estimates of the FNAIT at-risk population in racial and ethnic groups that may have been underrepresented in previously published studies. We believe that data from this study will better inform the size of the total FNAIT at-risk population.

We believe that screening for FNAIT risk can be performed routinely and cost effectively as part of standard prenatal testing provided to expectant mothers during pregnancy. Testing for maternal HPA-1 type and presence of the HLA-DRB3*01:01 allele could occur during the first trimester, at the same time as other routine blood work and risk screening, and we don't expect that an additional blood draw would be required. Importantly, U.S. and EU physicians have advised that our approach and timing for FNAIT screening would fit well within the established first trimester prenatal testing paradigm and could slot in at the same time as routine blood typing and Rh testing. Based on our global market research with maternal-fetal medicine specialists, obstetricians and payers, we believe there is a strong desire to both screen and provide preventive therapy to at-risk expectant mothers, if there were an approved product to prevent FNAIT and affordable screening tests.

We believe screening and preventive treatment can have a significant impact on this potentially devastating disease. For example, screening and treatment in Rh disease have been highly effective in reducing the number of affected births. In developed countries with access to prenatal testing and treatment, the prevalence of Rh disease is 2.5 per 100,000 compared to 276 per 100,000 worldwide. We believe that applying a similar approach to the prevention of FNAIT could lead to a significant reduction in the number of babies at risk for FNAIT.

We are working in partnership with Grifols Laboratory Solutions to include screen tests for maternal HPA-1 type, maternal HLA-DRB3*D1:01 status, maternal HPA-1a antibodies and fetal HPA-1 genotype in our clinical development program.

We intend to initiate a natural history trial of FNAIT in in which we plan to implement this screening paradigm in a broad population of expectant mothers of different racial and ethnic characteristics to identify those at risk of developing FNAIT. We also plan to use this trial to operationalize the FNAIT-risk laboratory test paradigm prior to implementing the laboratory tests in a future registration trial. We anticipate that data from this natural history trial, combined with data available from other literature-reported FNAIT screening studies, may be sufficient to serve as a basis for future regulatory discussions regarding the use of historical control data to support a future single arm Phase 2/3 registrational trial. We also believe that the experience in recruiting expectant mothers into this trial will accelerate recruitment into future FNAIT trials.

Our solution: RLYB211 and RLYB212

We are developing RLYB211, a polyclonal anti-HPA-1a antibody isolated from the plasma of women who developed HPA-1a antibodies due to a prior HPA-1 incompatible pregnancy, and RLYB212, a monoclonal anti-HPA-1a antibody developed from transformed memory B-cells isolated from a mother with severe FNAIT affected pregnancies. Our dual approach is rooted in our goal to provide a preventive therapy for FNAIT to mothers at risk as soon as practicable. We believe the early data generated from our ongoing RLYB211 Phase 1/2 clinical trial support the mechanism of action of RLYB211, and by extension that of RLYB212, to remove fetal HPA-1a platelets from HPA-1a negative expectant mothers and potentially prevent maternal alloimmunization, thereby eliminating the risk of FNAIT. We acquired all rights to both product candidates from Prophylix AS, or Prophylix, in 2019.

In November 2020, we announced that we dosed the first participant in our Phase 1/2 trial of RLYB211. We anticipate submitting an IND for RLYB212 in and initiating a Phase 1 trial by . We anticipate reporting additional data from our Phase 1/2 clinical trial for RLYB211 in .

We are prioritizing the development of RLYB212 based on the following:

- **Dose administration.** RLYB212 is dosed subcutaneously while RLYB211 is administered via intravenous bolus injection. Subcutaneous administration simplifies the treatment regimen for at-risk expectant mothers and is highly preferred by physicians in both the United States and EU, based on primary market research.
- **Pharmacokinetic profile.** Our pharmacokinetic modeling suggests that weekly subcutaneous administration of RLYB212 could maximize the capacity of RLYB212 to neutralize fetal antigen over the course of treatment compared to RLYB211, by maintaining higher trough levels and limiting fluctuations from peak to trough.

- **Standard manufacturing and stable supply**. Commercial quantities of RLYB212 are expected to be produced by standard monoclonal antibody production methods. RLYB211, however, is purified from plasma collected from women who developed HPA-1a antibodies due to a prior HPA-1 incompatible pregnancy. If RLYB211 is clinically successful in preventing FNAIT, the number of women with HPA-1a antibodies would decrease significantly, negatively impacting our ability to source a long-term supply of commercial product.

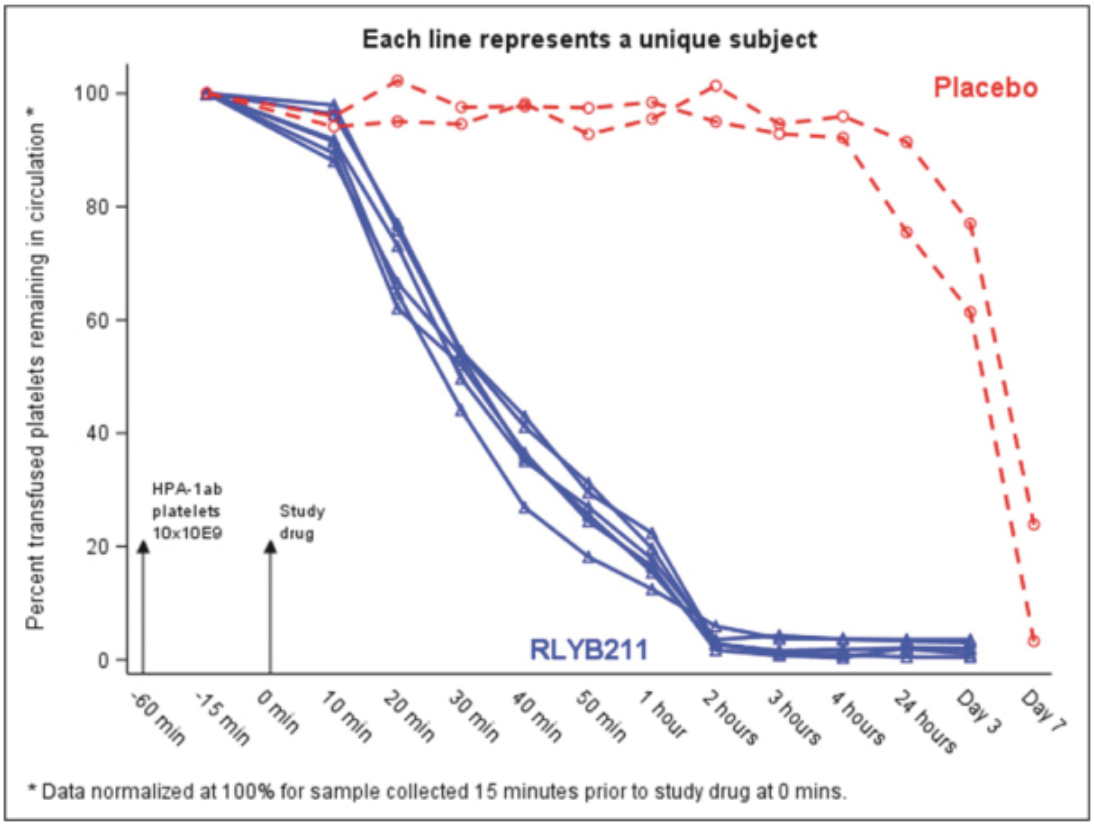
Clinical development of RLYB211: providing support for the RLYB212 approach

We are conducting a Phase 1/2 single-blind, placebo-controlled proof of concept trial designed to establish the dose of RLYB211 needed to rapidly clear HPA-1a positive platelets transfused to HPA-1a negative healthy male participants. In this trial, the elimination of transfused platelets is intended to serve as a surrogate for assessing the ability of RLYB211 to drive rapid elimination of HPA-1a positive fetal platelets from an expectant mother's circulation, thereby potentially preventing HPA-1a maternal alloimmunization and the occurrence of FNAIT in fetuses and newborns.

The trial consists of three cohorts, each investigating a different dose of RLYB211. In cohorts 1 and 2, platelet transfusion precedes single dose administration of either placebo or RLYB211 at 1,000 IU in cohort 1 and 4,000 IU in cohort 2. Data from cohorts 1 and 2 will be used to evaluate the trial's primary endpoint of time to platelet clearance. Data from cohort 3, investigating a 10,000 IU dose, will be used to establish the RLYB211 pharmacokinetic profile. Safety will be assessed across all cohorts. The trial is being conducted at the Clinical Research department of Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Branch for Translational Medicine and Pharmacology (TMP) in Frankfurt/Main, Germany in collaboration with the German Red Cross (Deutsches Rotes Kreuz) Blood Service Baden-Württemberg-Hessen in Frankfurt/Main, Germany.

In the first cohort of this trial, a dose of $10x10^9$ HPA-1ab platelets was transfused into healthy participants to simulate a fetal bleed into the maternal circulation one hour before a 1,000 IU dose of RLYB211. As illustrated below, administration of RLYB211 markedly accelerated the clearance of the transfused HPA-1a positive platelets compared with placebo, resulting in a half-life of mismatched platelets of 0.32 hours as compared to 65.29 hours with placebo (p value <0.001).

RLYB211 Led to Rapid Clearance of Transfused HPA-1a Platelets from Healthy Participants



Data from the first cohort provides proof of concept of the ability of anti-HPA-1a antibodies to rapidly clear HPA-1a positive transfused platelets in HPA-1a negative individuals. These data support the potential for the administration of an anti-HPA-1a antibody to drive the rapid elimination of HPA-1a positive fetal platelets from an expectant mother's circulation, thereby preventing HPA-1a maternal alloimmunization and the occurrence of FNAIT in fetuses and newborns.

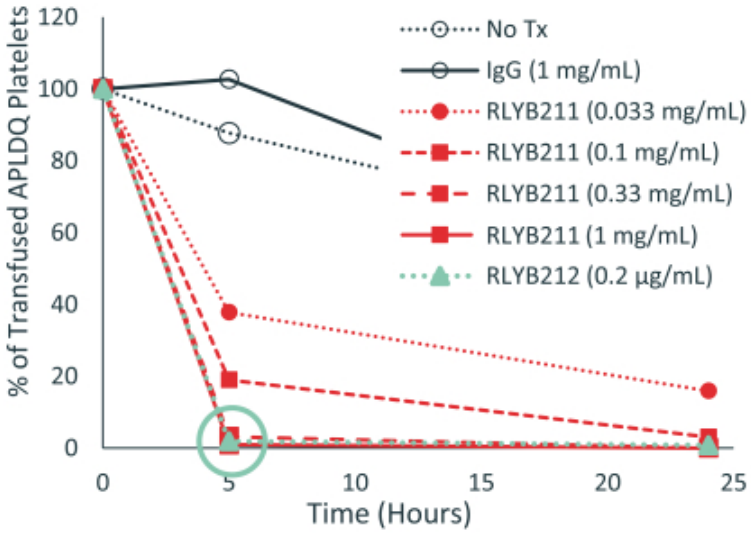
Given these positive results, we are now seeking a protocol amendment in which four healthy HPA-1a negative male participants will receive RLYB211 seven days prior to an HPA-1a positive platelet challenge. We believe this amendment will allow the trial to more closely mimic the situation in expectant mothers who would be eligible to receive an anti-HPA-1a antibody as a preventive treatment in anticipation of potential exposure to HPA-1a platelets from their fetuses. Data from this cohort are expected in .

RLYB212 preclinical data

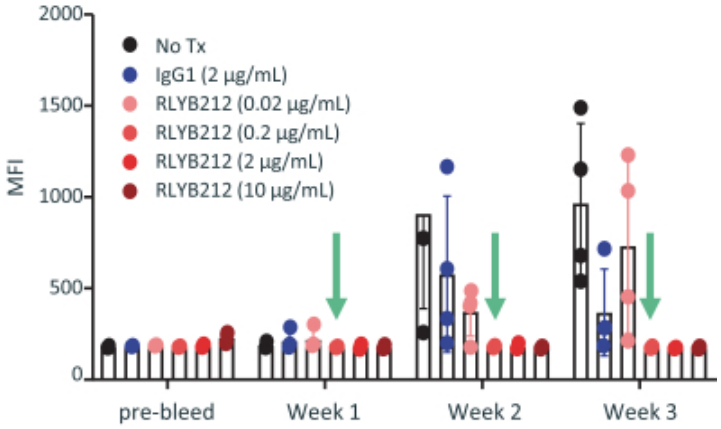
A mouse model of FNAIT has been created in which the amino acids comprising the HPA-1a antigen are reconstituted in the mouse gene. These transgenic mice (referred to as APLDQ mice based on the amino acid changes) recapitulate multiple aspects of FNAIT. Administration of anti-HPA-1a antibodies to APLDQ mice leads to destruction of APLDQ platelets and severe thrombocytopenia. Injection of platelets from APLDQ mice into wild-type mice can induce an HPA-1a specific immune response. Finally, wild-type female mice pre-immunized with APLDQ platelets, when bred with APLDQ male mice, give birth to severely thrombocytopenic pups, many of which exhibit an accompanying bleeding phenotype. Treatment of these pregnant female mice with IVIG resulted in lowering the level of anti-APLDQ antibodies in the fetus and a reduction in thrombocytopenia.

In a prophylactic treatment model, a single large bolus intravenous injection of 1 x 10^8 APLDQ platelets (equivalent to about one-sixth of the total blood volume in the host) was administered to wild-type mice. At a dose of 0.4 µg (yielding a peak concentration of approximately 0.2 µg/ml), RLYB212 was able to drive rapid and complete elimination of APLDQ platelets, as shown in the first graph below, and prevent a host antibody response, as shown in the second graph below. As shown in third graph below, this dose correlates to a concentration of RLYB212 projected to bind approximately 10% of the HPA-1a antigen present on the transfused APLDQ platelets. Thus, the approximately 10% receptor binding is sufficient to clear platelets and prevent alloimmunization.

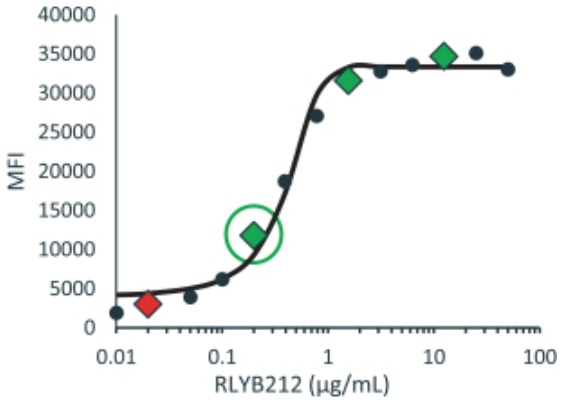
RLYB212 Induced Rapid Elimination of APLDQ Platelets



RLYB212 Prevented the Development of Antibodies to APLDQ Platelets



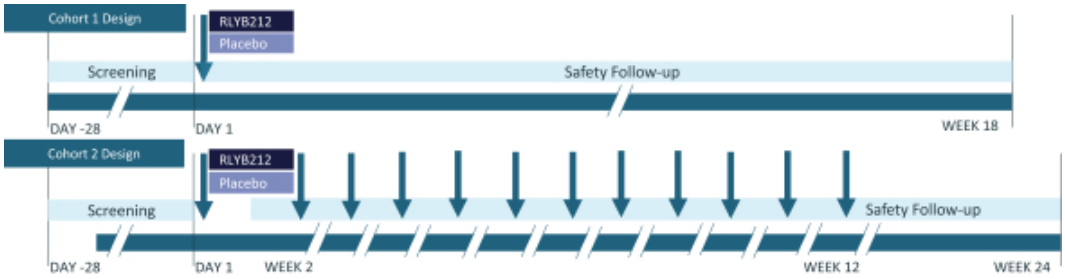
Ten Percent of APLDQ Platelets Bound by 0.4 µg Dose of RLYB212 at C_{max}



Clinical development of RLYB212

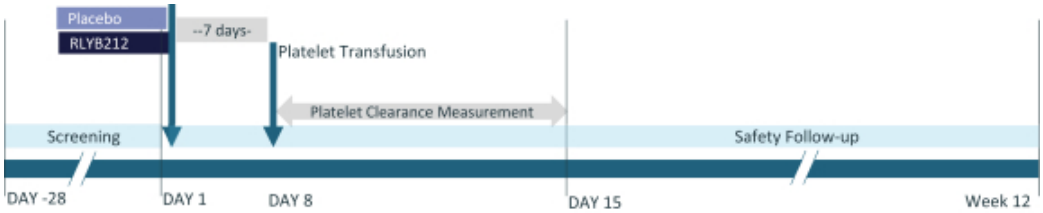
We anticipate initiating a Phase 1 single and multiple dose trial for RLYB212 in HPA-1a negative healthy participants by . The trial will evaluate the safety, tolerability and pharmacokinetics of RLYB212 following subcutaneous single dose administration and subcutaneous weekly doses for an estimated period of up to 12 weeks. The general design of the planned trial is illustrated below.

Design of the Initial Phase 1 Trial of RLYB212 in HPA-1a Negative Healthy Participants



A subsequent Phase 1b proof of concept trial will assess the ability of RLYB212 to rapidly eliminate transfused HPA-1a positive platelets from the circulation of HPA-1a negative healthy male participants in a design similar to that of the RLYB211 Phase 1/2 trial.

Design of the Phase 1b Trial of RLYB212 in Healthy Male Participants



Subject to successful completion of our planned Phase 1/1b trial and discussions with regulatory authorities, which have not yet occurred, we plan to conduct a registrational enabling Phase 2/3 trial of RLYB212 in expectant mothers at higher FNAIT risk.

RLYB116 for the treatment of disorders due to complement dysregulation

RLYB116 is an inhibitor of complement factor C5, a central component of the complement pathway, which plays a central role in innate immunity as well as shaping adaptive immune response. Dysregulation of the complement pathway has been implicated in the pathogenesis of a growing number of diseases, making it an attractive target for therapeutic intervention. Antibody inhibitors of C5 have been successfully developed to treat diseases caused by immune dysfunction, including PNH, aHUS, refractory gMG and relapsing NMOSD. Despite approved products for these indications, we believe there remains an unmet need in patients with these diseases for therapies that are more patient-friendly and accessible. RLYB116 is an Affibody® molecule, which is an antibody mimetic protein that has a much smaller molecular weight than a traditional antibody and may also be easier and less costly to produce. In contrast to C5-targeted antibody therapeutics that are administered intravenously, RLYB116 has the potential to be administered as a small volume subcutaneous injection. Additionally, RLYB116 is linked to an albumin binding domain, which may extend its half-life. We view RLYB116 as a potential pipeline-in-a-product. Our lead indications for RLYB116 are PNH and acetylcholine receptor, or AChR, antibody positive gMG. However, we plan to evaluate the development of RLYB116 for the treatment of additional rare complement-mediated diseases. We believe RLYB116 could potentially enable more patients suffering from PNH and gMG to be treated globally and could also provide a meaningful therapeutic impact for patients suffering from a broad number of other diseases of complement dysregulation.

The complement system

The complement system includes over 30 proteins in plasma and on cell surfaces that support the body's adaptive or antibody-based immune system in the destruction of pathogenic bacteria. Complement proteins circulate in the blood in an inactive form prior to activation in response to infection. Activation occurs through a pathway of proteolytic cleavage events initiated by pathogen recognition and resulting in pathogen destruction. Three complement pathways are known and are referred to as the classical, lectin and alternative pathways. In the classical pathway, antibodies bind to antigens, which in turn trigger a protease cascade that activates complement protein C3 and then complement protein C5. Activation of C5 convertase generates C5b which can initiate formation of membranes pores and subsequent lysis of cells. The binding of C5b to host cells is normally prevented by the presence of specific glycoproteins on the cell surface.

PNH disease background

PNH is a rare, potentially life-threatening hematologic disease characterized by complement-mediated destruction of red blood cells, or hemolysis. Early signs of PNH include hemoglobinuria, or dark colored urine, resulting from excretion of hemoglobin from lysed red blood cells, which is more prominent in the morning and decreases during the day. More serious symptoms of PNH include anemia, excessive weakness, fatigue, severe abdominal pain, severe headaches and recurrent infections. PNH leads to over a 60-fold increase in the risk of venous thromboembolism compared to the general population and these thrombotic events lead to between 40% and 67% of deaths in PNH patients. Approximately two thirds of patients with PNH develop chronic kidney disease, or CKD, and kidney failure is the cause of death in 8% to 18% of PNH patients. In the absence of disease-modifying treatment, PNH results in the death of approximately 35% of affected individuals within five years of diagnosis. An analysis conducted in 2006 estimated that there were approximately 4,700 patients living with PNH in the United States.

In patients with PNH, blood precursor cells acquire a mutation in a gene encoding a protein that anchors a specific set of proteins on the cell surface. When these proteins, known as glycoproteins, are in place on the blood precursor cells, then the cells are protected from immune attack. However, in patients with PNH, these mutations cause the absence of these glycoproteins and renders red blood cells susceptible to destruction by the complement pathway. Once the cells are destroyed, by a mechanism known as lysis, the hemoglobin from these cells is then removed from circulation by the kidneys and excreted in the urine. Excess hemoglobin and additional proteins from lysed red blood cells causes the kidney damage seen in most PNH patients. The observed increase in the rate of thrombosis in PNH patients is believed to be related to altered platelet function as well as to other activities associated with the C5a protein, such as vasoconstriction and increases in inflammation.

Current treatments for PNH and their limitations

The only curative treatment currently available for PNH is a stem cell transplant from a related donor. However, this procedure is associated with significant risk and is typically used only in those patients with severe disease, such as life-threatening thrombosis or dangerously low blood counts. Various supportive therapies include anticoagulants, red

blood cell transfusions and supplements of iron and folate. These therapies provide some relief from symptoms but do not address the underlying cause of the disease.

There are two approved disease-modifying drugs for PNH: eculizumab, marketed by Alexion as Soliris; and ravulizumab, marketed by Alexion as Ultomiris. Both of these products are antibodies that bind to complement C5 and prevent its cleavage by C5 convertase to C5a and C5b, thus blocking a central step in the complement pathway. Both products are roughly equivalent in their ability to block C5 cleavage, prevent hemolysis, minimize the need for transfusions and to stabilize hemoglobin.

Eculizumab and ravulizumab are each administered intravenously by healthcare professionals: eculizumab at biweekly intervals and ravulizumab at eight-week intervals. Despite the requirement for intravenous administration and limitations on access, wide adoption of these drugs has led to worldwide sales of eculizumab and ravulizumab which in 2020 exceeded $5 billion. We believe that a product that works through a similar mechanism but with a more convenient route of administration and improved patient access has the opportunity to further transform PNH therapy for patients.

Potential benefits of our approach

We are pursuing PNH as part of our initial development strategy for three reasons. First, PNH has a well-understood disease pathophysiology driven by complement, providing a sound biological rationale for a C5-targeted intervention. Second, PNH offers the opportunity for early clinical validation using objective endpoints, including impact on lactate dehydrogenase, a component of red blood cells that is increased in circulation as a result of hemolysis. And third – and most importantly – we believe that with a patient-friendly and accessible therapy, RLYB116 could potentially provide transformative therapeutic impact for unserved and underserved patients with PNH globally.

Generalized myasthenia gravis disease background

Generalized myasthenia gravis is a potentially life-threatening, rare autoimmune neuromuscular disorder. Patients with gMG develop antibodies that attack critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This inhibition leads to muscle weakness, which can occur in ocular muscles leading to droopy eyelids as well as blurred or double vision due to partial paralysis of eye movements and in the muscles in the neck and jaw, causing problems in chewing and swallowing. gMG can also cause respiratory problems, speech difficulties and weakness in skeletal muscles leading to problems in limb function. The symptoms of the disease can be transient and can remit spontaneously in the early stages of the disease. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Up to 20% of gMG patients experience respiratory crisis at least once in their lives. During crisis, a decline in respiratory function can become life-threatening and often requires intubation and mechanical ventilation, and hospital stays for patients in crisis last a median of seventeen days. According to a comprehensive epidemiological study of gMG in western Denmark form 1975-89, From the time of diagnosis, the overall survival rates at 3, 5, 10 and 20 years are estimated to be 85%, 81%, 69% and 63%, respectively. In addition, patients with gMG suffer from poor quality of life due to the impact of their disease on physical function as well as the burden of treatment-related adverse events.

The most common proteins that have been targeted by these autoimmune antibodies are AchR, which are within the neuromuscular junction and bind to the acetylcholine neurotransmitter released by the nerve; and muscle-specific kinase, or MuSK, a tyrosine kinase involved in propagating neuronal signals. The presence of these autoimmune antibodies blocks the signaling from neurons to muscles which results in outward signs of muscle weakness.

The pathology in gMG arises not only from interrupting signal transduction, but from physical destruction of the post-synaptic membrane through activation of the complement pathway. Over 80% of patients with gMG have antibodies to AchR and these antibodies can lead to complement-driven lysis of the post-synaptic membrane. Eculizumab is approved for the treatment of AchR antibody-positive gMG based on its ability to lead to significant improvements in the Myasthenia Gravis-Specific Activities of Daily Living scale and the Quantitative Myasthenia Gravis score which measures muscle weakness.

In the United States, the prevalence of gMG is estimated to be 14,000 to 20,000 per 100,000, with as many as 60,000 patients estimated to be living with the disease. As with many autoimmune diseases, there are no known genetic alterations that specifically cause gMG. In most patients, the disorder arises spontaneously. Approximately

3% of patients have a primary relative with gMG, suggesting that there are genetic factors that may predispose development of the disease, but these genes have yet to be identified.

Current treatments for gMG and their limitations

In the first-line setting, patients presenting with symptomatic gMG are commonly treated with acetylcholinesterase inhibitors such as pyridostigmine in order to improve neuromuscular transmission. As the disease progresses, patients may receive immunosuppressive therapies such as azathioprine, glucocorticoids, mycophenolate and cyclosporine. These therapies are used off-label for patients with gMG and unfortunately, each of these can be associated with substantive treatment burden and in some cases, can lead to disease worsening. Soliris (eculizumab) has been approved in the United States, EU, Japan and other markets for the treatment of patients with refractory gMG who are anti-AChR positive. Substantive symptom improvements have been noted with eculizimab treatment at the first assessment at one week after first dose administration. Rituximab may also be used off-label and is believed to have more benefit in patients with gMG with anti-MuSK antibodies compared to those with anti-AChR antibodies.

For patients with severe myasthenia or recurrent exacerbation and crisis, there are a number of methods utilized to reduce circulating IgG antibodies, as published studies have shown that decreases in circulating IgG antibody levels are correlated with increased relief of symptoms and decreases in the length of hospital stays. These procedures include: plasma exchange, a process whereby blood is taken from a patient and IgG antibodies are physically removed from the plasma before it is returned to the patient; and administration of IVIG, which provides therapeutic benefit through multiple hypothesized mechanisms, including the saturation of the FcRn receptor, which may lead to increased degradation of the endogenous autoimmune antibodies. Both procedures are burdensome for patients and repeat administration is usually required to obtain significant reduction in symptoms. In addition, the large volumes of intravenous fluid associated with the administration of IVIG can lead to pulmonary edema and kidney complications in elderly patients.

Potential benefits of our approach

We are pursuing AChR antibody positive gMG as part of our initial development strategy for two reasons. First, complement overactivity is known to contribute to the disease pathophysiology of gMG, again providing a sound biological rationale for a C5-targeted intervention. Second – and most importantly – we believe there is significant unmet need that we can address. We believe the convenience of subcutaneous self-administration may enable treatment of a broad population of gMG patients at both earlier and late stages of disease.

Our solution: RLYB116

RLYB116 is an engineered biologic known as an Affibody® molecule, which we acquired rights to from Swedish Orphan Biovitrum AB, or Sobi. RLYB116 has been designed to be optimized for C5 binding, stability and long half-life in serum. Potential benefits of RLYB116 include:

- **Subcutaneous administration**. The low molecular weight allows for a higher concentration of active molecules than antibodies in an equivalent volume. This increases the probability of being able to deliver RLYB116 in a volume suitable for subcutaneous administration.
- **Efficiency of manufacturing**. RLYB116 is expressed in *E coli*, providing for a more streamlined manufacturing process compared to antibodies or other biologics expressed in mammalian cell culture, which typically require larger scale and longer manufacturing times.
- **Less frequent dosing**. Linkage to an albumin binding domain may lengthen the dosing interval of RLYB116 by extending the biological half-life.
- **Broader indication opportunity**. Linkage to an albumin binding domain also may improve distribution to tissues throughout the body creating the potential for additional tissue targets and indications.
- **Potentially lower risk of treatment conversion**. Due to 1:1 binding to C5, there is potentially lower risk of immune complex formation when switching from treatment with an antibody.
- **Favorable stability.** The Affibody® platform provides the possibility of delivering highly stable and soluble therapeutic agents that allow for high-concentration low-volume products.

Pharmacodynamic properties of RLYB116

An ex vivo hemolytic inhibition assay suggests that RLYB116 may inhibit C5-mediated red blood cell destruction at a dose that could be clinically useful.

Clinical development plans for RLYB116

We intend to submit a CTA for RLYB116 in , with the goal of initiating a Phase 1 clinical trial of RLYB116 in healthy adult participants by . This trial will evaluate the safety, tolerability and pharmacokinetics of RLYB116 following subcutaneous administration of a single dose and multiple doses. We also plan to incorporate a measure of pharmacodynamic activity into the single and multiple ascending dose segments of the trial. The trial is planned to enroll up to 48 participants in the single ascending dose segment and evaluate up to 6 dose levels. The multiple ascending dose segment of the trial is planned to enroll up to 84 participants and up to 7 dosing strategies. A Phase 1b trial is planned in patients with PNH to assess the effect of RLYB116 on measures of pharmacodynamic activity as well as safety and pharmacokinetics. We anticipate conducting subsequent trials in patients with PNH and AChR antibody positive gMG, which are both indications in which C5 inhibition has been clinically validated. Beyond these initial indications, we plan to evaluate the development of RLYB116 for the treatment of additional rare complement-mediated diseases, given the growing numbers of diseases understood to be mediated by complement dysregulation.

RLYB114 for the treatment of ophthalmic disorders

RLYB114 is comprised of a C5-targeted Affibody® molecule conjugated to polyethylene glycol, or PEG. The addition of PEG to protein therapeutics is a well-established method of extending the half-life and reducing the immunogenicity of these molecules in the body. Given the role of the complement system in retinal and ocular pathology, we are exploring a range of ophthalmic diseases, including inflammatory and degenerative disorders, for the development of RLYB114.

Potential role of complement in ocular diseases

Photoreceptors and the retina encounter a number of innate immune activators. Dysregulation of the complement system may drive ocular inflammation and contribute to vision loss in multiple diseases such as age-related macular degeneration, or AMD. A number of genetic studies have shown links between alterations in genes encoding various complement factors and the risk of development of AMD. Several clinical trials of inhibitors of the complement pathway including C5 inhibitors have been conducted, with reports of modest efficacy. Reasons for this limited efficacy are unknown but could include the disease stage treated, level of intervention in the complement pathway, drug delivery mechanism and ability of the therapeutic to cross Bruch's membrane to the retinal pigment epithelium.

Preclinical studies

Pharmacologic studies of RLYB114 in rabbits following intravitreal administration demonstrated that it had a half-life and tissue distribution within the eye comparable or superior to other wet AMD therapeutics. RLYB114 was also well tolerated in this study with no major signs of ocular toxicities.

Our solution: RLYB114

We plan to test multiple PEG moieties for C5 affinity and hemolysis inhibition in vitro, and characterize the pharmacokinetic and safety profile after intravitreal administration in a rabbit model. Based on this series of nonclinical experiments, we expect to select a lead candidate for GLP toxicology studies and GMP manufacturing to support a regulatory submission in advance of the conduct of a first-in-human study.

Artificial Intelligence drug discovery collaboration with Exscientia

We have established a partnership with Exscientia, an artificial intelligence, or AI, and machine learning drug discovery company. Exscientia has built dedicated AI systems that learn from a wide range of data and apply enhanced knowledge through iterations of design. Our partnership currently consists of two joint ventures that each focus on the discovery and development of small molecules for the treatment of patients with rare metabolic diseases. The first of these joint ventures is targeting ENPP1, an enzyme involved in regulating extracellular levels of pyrophosphate, a natural inhibitor of calcium mineralization in bone formation, for the treatment of patients with HPP. Our second joint venture with Exscientia is focused on identifying a small molecule modulator for the treatment of patients with an undisclosed rare metabolic disorder.

Exscientia is a leader in the application of artificial intelligence to drug discovery. Their proprietary platform is built upon validated artificial intelligence technology that has delivered multiple candidates to the clinic, including the first ever AI-designed therapeutic candidate. Their approach is designed to streamline the drug discovery process by significantly reducing the number of compounds synthesized, thereby reducing the time and cost of drug discovery. For Rallybio, this creates an attractive opportunity to continue building an early pipeline through a multi-target, shared-risk, joint venture with Exscientia, combining their rapid and streamlined target execution process with our rare disease development expertise and track record of delivering therapies to patients.

RE Ventures I: ENPP1 inhibitor program for the treatment of patients with hypophosphatasia

We are developing an ENPP1 inhibitor for the treatment of patients with HPP, a rare, potentially life-threatening genetic disease characterized by mutations in the ALPL gene. These mutations lead to diminished activity of the TNSALP enzyme and the accumulation of inorganic pyrophosphate, or PPi, which inhibits bone mineralization causing multiple skeletal pathologies. ENPP1 is a Type II transmembrane glycoprotein that cleaves ATP, producing PPi, and is a major source of PPi production in cells. We believe that controlling inhibition of ENPP1 may reduce PPi levels and restore balance within the bone mineralization process.

HPP disease overview

HPP is an inherited disorder that affects the development of bones and teeth. More than 300 mutations in the ALPL gene associated with HPP have been identified. These mutations are associated with a wide range of disease severity. The most severe forms of the disorder tend to occur before birth and in early infancy. These infants have short limbs, an abnormally shaped chest, soft skull bones, poor feeding, failure to gain weight, respiratory complications and high levels of calcium in the blood, or hypercalcemia, which can lead to life-threatening complications. In other cases, the disease is not recognized until later in childhood where it manifests as rickets, pain, decreased mobility, deficits of growth and fractures. Children with less severe HPP can experience early loss of primary teeth and may have short stature with bowed legs or knock knees, enlarged wrist and ankle joints and an abnormal skull shape. Findings in adults include a softening of the bones, known as osteomalacia, and recurrent fractures in the foot and thigh bones that can lead to chronic pain. The incidence of HPP has been reported to be 1 in 100,000 (United States and Canada) to 1 in 300,000 (EU) for severe disease and 1 in 6,370 (EU) for less severe forms.

The various manifestations of HPP are caused by the combination of a lack of phosphate and an excess of PPi due to a deficiency of TNSALP, the enzyme that converts PPi to phosphate. This deficiency negatively impacts bone formation by reducing the hydrolysis of PPi to phosphate required for normal bone formation, resulting in a build-up of PPi, a potent inhibitor of mineralization.

Strensiq, an enzyme replacement therapy marketed by Alexion, is the only approved therapy to treat patients with perinatal-, infantile- and juvenile-onset HPP. The therapy has been shown to lead to significant improvements in morbidity and mortality in patients with perinatal- and infantile-onset HPP, and improvements in morbidity for patients with juvenile-onset HPP. However, Strensiq has limitations, including its dosing regimen and patient access. Strensiq is administered by subcutaneous injection either three or six times per week using a weight-based dosing scale, which can be both onerous and painful for patients. Furthermore, a population of adult patients may have difficulty accessing the therapy given reimbursement dynamics in countries around the world as a result of weight-based dosing that drives high costs for heavier patients.

Our solution: an ENPP1 small molecule inhibitor

We are developing an orally available, small molecule ENPP1 inhibitor designed to reduce PPi levels through the controlled inhibition of ENPP1, which we hypothesize may restore the balance of PPi and phosphate needed to promote bone mineralization. This program is in its early stages and preclinical and clinical development is required. If an ENPP1 inhibitor is successfully advanced through clinical development and obtains marketing approval, we believe that an oral small molecule ENPP1 inhibitor, administered as a stand-alone therapy or in combination with Strensiq, could have significant benefit in managing HPP and improving the lives of patients.

We are currently optimizing our lead molecules and anticipate selecting a development candidate by .

Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development of products that may be like our product candidates or address similar markets. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. The success of our product candidates, if approved, is likely to be a result of their efficacy, safety, convenience, price, the level of biosimilar or generic competition and/or the availability of reimbursement from government and other third-party payors.

FNAIT. There are currently no approved therapies for the prevention or treatment of FNAIT. In one frequently used approach to manage pregnancies where the mother is known to have a history of FNAIT, physicians administer high levels of IVIG. Companies that currently market IVIG include ADMA Biologics, Bio Products Laboratory, CSL Behring, Grifols, Kedrion Biopharma, Leadiant Biosciences, Octapharma and Takeda Pharmaceutical Company Limited.

PNH. The only curative treatment currently available for PNH is a stem cell transplant from a related donor. However, this procedure is associated with significant risk and is used only in those patients with severe disease, such as life-threatening thrombosis or dangerously low blood counts. Various supportive therapies include anticoagulants, red blood cell transfusions and iron and folate supplements. These therapies provide some relief from symptoms but do not address the underlying cause of the disease. There are two approved disease-modifying drugs for PNH: eculizumab, marketed by Alexion as Soliris; and ravulizumab, marketed by Alexion as Ultomiris. Both of these products are antibodies that bind complement C5. There are several companies in mid- to late-stage clinical trials developing treatments for PNH. These include Akari Therapeutics, Alnylam Pharmaceuticals, Apellis Pharmaceuticals, Novartis, Regeneron Pharmaceuticals and Roche.

MG. Very early-stage MG is symptomatically treated by the use of acetylcholinesterase inhibitors such as pyridostigmine bromide, marketed as Mestinon by Bausch Health. Eculizumab is also approved for the treatment of generalized MG in patients who are positive for anti-AChR antibodies. There are several other companies developing assets in mid- to late-stage clinical development for the treatment of MG using a variety of approaches and modalities. These companies include Argenx SE, Catalyst Pharmaceuticals, CureVac, Horizon Therapeutics, Immunovant, Inc. and UCB Biopharma.

HPP. There is one approved treatment for HPP, asfotase alfa, marketed by Alexion as Strensiq, is an alkaline phosphotase enzyme replacement therapy, and the only approved therapy for the treatment of perinatal-, infantile- and juvenile-onset HPP. Alexion is developing a second generation enzyme replacement therapy, which is currently in preclinical development, and AM Pharma has an active discovery program. There are several companies pursuing ENPP1 small molecule inhibitors for the treatment of cancer, including AbbVie, Inc., Angarus Therapeutics, Avammune Therapeutics, and Stingray Therapeutics. We are not aware of other small molecule inhibitors in development for the treatment of patients with HPP.

Many of our competitors may have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, commercial infrastructure, and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Intellectual Property

Our success depends, in part, on our ability to obtain, maintain, defend, and enforce patent rights and other intellectual property rights that protect our business, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable intellectual property rights of others. In addition to our efforts to protect our product candidates and methods of using them, we also seek to secure or acquire patent rights regarding other

products and methods that are important to the general development of commercial products. We utilize a multi-layered approach that includes acquiring intellectual property rights through purchase or exclusive license, filing and prosecuting U.S. and foreign patent applications directed to our own innovations, and developing and protecting proprietary know-how to maintain our competitive position.

Our ongoing efforts to secure patent rights that protect our business constitute a key component of our business strategy. We also strive to protect as trade secrets or confidential know-how, certain aspects of our programs and technological innovations that are commercially valuable but are not amenable to or appropriate for patent protection. We achieve this, in part, through the use of confidentiality agreements with our employees, consultants, scientific advisors, collaborators, licensors, and contractors, and by striving to maintain physical security of our premises and digital security of our electronic information and technology systems.

Notwithstanding our commitment to protecting our intellectual property rights, we, like other pharmaceutical and biopharmaceutical companies, are subject to several sources of uncertainty that can affect those rights. For example, we cannot be certain that any patents that we currently own or in-license, or that we may own or in-license in the future, will not be challenged, held to be invalid and/or unenforceable, have the scope of their claims narrowed, or be circumvented by others. Nor can we be certain that such patents will successfully protect our products or our business from competition.

Similarly, with respect to patent applications that are currently pending, or that may be pending in the future, we cannot be certain that such patent applications will result in the issuance of granted patents, or of patent claims with the desired claim scope. In order to secure an issued patent, an invention claimed in a patent application must meet certain legal requirements for patentability, which differ between countries based on each country's particular patent laws.

In addition, because of the significant amount of time required for clinical development and regulatory review of products candidates, we cannot be certain that any of our product candidates will be commercialized while there is significant patent term remaining on patents relating to those products. The term of a patent depends upon the legal requirements for determination of patent term in the country in which that patent is granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting the patent. Likewise, a patent's term may be shortened if it is terminally disclaimed over an earlier-expiring patent with a common owner or inventor.

The term of a U.S. patent relating to an approved drug product may also be extended to compensate the patentee for delays due to the regulatory approval process. Such a patent term extension, or PTE, cannot exceed five years, and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Furthermore, the term can be extended for only one patent applicable to each regulatory review period and only those claims covering the approved product, or a method for using it or manufacturing it, may be extended. In the future, if any of our product candidates receive approval by the U.S. Food and Drug Administration, or the FDA, we expect to apply for PTE on any issued patents covering those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that we will benefit from any PTE or favorable adjustments to the terms of any patents we currently own or in-license or that we may own or in-license in the future.

In addition to and separate from patent exclusivity, the FDA may also grant marketing exclusivity of varying lengths in connection with the approval of a New Chemical Entity (5 years), Biologic (12 years), or Orphan Drug indication (7 years). Marketing exclusivity may also be granted for new clinical studies (3 years) and pediatric studies (6 months) on approved drugs. Depending on the length of the regulatory approval process and the ability to make use of the procedures for obtaining PTE, any FDA exclusivity period may in part or in whole overlap with any patent exclusivity to which we are entitled. We intend to pursue relevant marketing exclusivities in the US and in foreign countries in which any candidate product is approved. However, we cannot be certain that any such exclusivities will be granted or, if granted, will insulate our commercial product(s) from competition.

With respect to trade secrets, while we have confidence in the protective measures that we employ, such measures can be breached, and we may not have adequate remedies for any such breach. We also cannot be certain that any of our activities will not be subject to the intellectual property rights of others.

As of March 31, 2021, we owned two patent families that were acquired from Prophylix and relate to the current product candidates in our FNAIT prevention program, RLYB211 and RLYB212. The patent family covering RLYB212 and its use in treating and preventing FNAIT includes patents issued in Australia, Europe, Mexico, Russia and the United States. Patent applications in this family are pending in Brazil, Canada, Israel and the United States. The granted patents in this family will expire in 2035, excluding any PTA or PTE that may be awarded. The patent family covering administration of RLYB211 for the prophylactic treatment of FNAIT includes patents issued in the United States, Europe and Canada. The foreign patents and one of the U.S. patents will expire at the end of 2026, while the other U.S. patent expires in November 2030 due to a PTA granted by the U.S. Patent and Trademark Office. In addition, we exclusively in-license certain rights to technology from Versiti Blood Research Institute Foundation, Inc. pertaining to a mouse model of FNAIT.

As of March 31, 2021, we owned two patent families relating to the current product candidates in our complement program, RLYB114 and RLYB116, and certain aspects of their use. These two patent families, which were acquired from Sobi, currently include three granted U.S. patents and one pending U.S. patent application, with granted patents and/or pending patent applications in more than 25 additional countries worldwide. The granted U.S. patents in these two patent families are scheduled to expire between 2033 and 2034, excluding any PTA or PTE. We have also in-licensed certain patent rights relating to our current product candidates from Affibody, including patent rights relating to the Affibody® molecule technology and Albumod albumin binding molecule technology.

License Agreement

Product License Agreement with Affibody AB

In March 2019, our subsidiary IPC Research, LLC, or IPC Research, and Sobi entered into a Contract Assignment Agreement pursuant to which Sobi assigned to, and IPC Research assumed, all obligations in a certain Product License Agreement, referred to herein as amended as the PLA, between Sobi and Affibody AB, or Affibody, dated March 9, 2012, as amended on January 1, 2018 and December 22, 2020.

Pursuant to the PLA, we obtained a license to the Affibody® platform technology and a particular albumin binding domain, or ABD, in order to further develop and commercialize certain Affibody ligands, which we are now developing as RLYB116 and RLYB114.

Under the PLA, Affibody grants us (a) a non-exclusive right under certain patents to use the Affibody ligands alone or as a fusion protein and (b) an exclusive right to use the Affibody ligands alone or as a fusion protein, in each case, for human therapeutic use. Affibody also grants us (a) a non-exclusive right under certain patents to use the ABD in combination with the Affibody ligands as a fusion protein and (b) an exclusive right to use the ABD solely in combination with the Affibody ligands as a fusion protein, in each case, for human therapeutic use. Affibody grants us a non-exclusive license under applicable know-how needed to practice the rights and licenses granted under the PLA. All licenses to us are sublicensable, provided that each sublicense is consistent with the terms and conditions of the PLA. Under the PLA, Affibody has an exclusive right under any product patents, which are a category of certain patents that we own, to use the specific Affibody ligands outside of human therapeutics and a non-exclusive right under know-how needed to practice the Affibody ligands outside of human therapeutics.

Under the PLA, Affibody is the exclusive owner of, and controls prosecution, maintenance, and defense of intellectual property covering, platform technology. We are the exclusive owner of, and control prosecution, maintenance, and defense of intellectual property covering, product technology. Affibody agrees to disclose to us any improvement to the Affibody technology that it deems commercially reasonable for us to practice and grants us an option to license any such improvement. We have the first right to enforce product patents against a third-party infringer and Affibody retains the first right to enforce any other licensed patent. We agree to not provide or make available any Affibody Ligand to a third-party on a standalone basis except for research purposes or to commercialize a licensed product.

We agree to use commercially reasonable efforts to develop and commercialize a licensed product. We also will pay Affibody certain regulatory milestones up to an aggregate amount of €7.5 million and (a) a mid-single-digit royalty on annual net sales of products if such products are covered by a valid claim of a product patent or a platform patent or (b) low-single-digit royalties on annual net sales of products that are not covered by any such valid claim. Our obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of (a) the expiration of the last-to-expire valid claim of a patent covering a licensed product or (b) the 10th anniversary following first commercial sale of such product in such country.

The PLA will terminate when we are no longer obligated to pay royalties to Affibody. Either party may terminate the PLA upon material breach of the PLA by the other, subject to a cure period, or immediately in the case of the other party's insolvency, bankruptcy or a similar event. Affibody may terminate the PLA immediately if we or any of our affiliates or third party transferees commences any proceeding challenging the validity of the licensed patents or any of Affibody's other patents or challenging the confidentiality or substance of the licensed know-how or licensed technology. We may terminate the PLA for convenience upon 90 days prior written notice and upon payment of any amounts due to Affibody through the effective date of such termination.

If Affibody terminates the PLA or if we terminate the PLA for convenience, (a) all rights and licenses granted under the PLA will terminate, (b) at Affibody's request, we must transfer all rights to the product technology free of charge to Affibody and (c) we must return or destroy all of Affibody's confidential information. Furthermore, if we terminate for convenience, we must grant Affibody an exclusive, royalty free perpetual right to use all regulatory filings, approvals and data provided to regulatory authorities in support of such filings or approvals that relate to the licensed product. However, if we terminate the PLA as a result of Affibody's material breach of the PLA or its insolvency or bankruptcy, we will retain our license and rights under the PLA, provided that we will remain bound by certain obligations under the PLA with respect milestone payments, royalties (subject to a reduction in rate, in the case of material breach), audits and indemnity.

Asset Purchase Agreements

Asset Transfer Agreement with Swedish Orphan Biovitrum AB

In March 2019, through IPC Research, we entered into an agreement with Sobi, pursuant to which we acquired the right, title and interest in assets related to certain C5 inhibitor compounds. We are currently developing the assets acquired from Sobi as RLYB116 and RLYB114.

We paid Sobi an upfront purchase price of $5.0 million and we are obligated to pay Sobi an aggregate amount of up to $51.0 million upon achievement of certain development milestones and an aggregate amount of up to $65.0 million upon achievement of certain sales milestones.

We also will pay Sobi tiered, low single-digit royalties on annual net sales to third parties for products containing any compound transferred under the agreement as an active ingredient. Our obligation to pay royalties expires, on a country-by-country and product-by-product basis, on the later of (a) the 10th anniversary following first commercial sale of such product in such country and (b) the expiration date in such country of the last to expire of any issued patent included in the patent rights acquired from Sobi that includes at least one valid claim covering the sale of such product in such country.

We are obligated to use commercially reasonable efforts to research, develop and exploit at least one product that contains a compound transferred under the agreement as an active ingredient in each of the United States, EU and Japan.

If, prior to the commercial launch in the United States of the first product containing the compounds, we decide to divest our rights in the assets acquired from Sobi or to terminate all research, development and commercialization activities in respect of the acquired compounds, we must notify Sobi and negotiate in good faith with Sobi a possible business transaction relating to the assets. This right of negotiation will not apply to a transaction to sell all or substantially all of the assets of IPC Research or an affiliate of IPC Research, a pledge of the assets as collateral or a sale or transfer of the assets to an affiliate of IPC Research that agrees to be bound by the right of negotiation.

Asset Purchase Agreement with Prophylix AS

In June 2019, though our subsidiary Rallybio IPA, LLC, or Rallybio IPA, we entered into an agreement with Prophylix to acquire all of Prophylix's rights, title and interest in, to and under all assets, properties and rights related to Prophylix's plasma-derived anti-HPA-1a immunoglobulin, which we are developing as RLYB211, and Prophylix's monoclonal antibody, which we are developing as RLYB212.

We paid Prophylix an upfront purchase price of approximately $1.2 million and reimbursed Prophylix approximately $1.8 million for certain manufacturing costs incurred by Prophylix. We are obligated to pay Prophylix an aggregate of up to $19.0 million upon achievement of certain development milestones and an aggregate of up to $20.0 million upon achievement of certain sales milestones.

We also will pay Prophylix tiered, mid-single-digit royalties on annual net sales of products containing the monoclonal antibody and tiered mid-to-high-single and low-double-digit royalties on annual net sales of products containing plasma-derived anti-HPA-1a immunoglobulin, subject to certain offsets for royalties payable under certain third-party licenses. Furthermore, the then-applicable royalty rate will be reduced by a mid-double digit percentage for the remaining royalty term on a country-by-country basis if it becomes reasonably likely that the Prophylix patents may no longer be enforceable in such country due to a challenge of the enforceability of the patents or the enforceability of the royalty payments following the expiration of all valid claims of the patents in such country. Our obligation to pay royalties terminates on a country-by-country and product-by-product basis on the later of (a) the expiration of the last-to-expire valid claim of a Prophylix patent covering a product, (b) expiration of regulatory exclusivity for the product in such country or (c) the 10th year anniversary following first commercial sale of such product in such country.

In the event the FDA grants a priority review voucher for one of our product candidates developed using the technology acquired from Prophylix, we will pay Prophylix either: (a) if we sell such priority review voucher to a third-party within 12 months of its receipt, a mid-double digit percentage of the proceeds we receive from the sale, net of taxes, or (b) if we do not sell the priority review voucher to a third-party within 12 months of receipt, a mid-double digit percentage of the fair market value of the priority review voucher as determined in accordance with the agreement.

We are obligated to use commercially reasonable efforts to develop and commercialize products containing plasma-derived anti-HPA-1a immunoglobulin in the United States and in at least one major European market. The agreement provides that if we provide notice to Prophylix that we determined that commercialization of products containing plasma-derived anti-HPA-1a immunoglobulin is not feasible due to an insufficient plasma supply following our continued and diligent efforts to obtain a sufficient plasma supply, then our obligation to develop products containing plasma-derived anti-HPA-1a immunoglobulin will cease, and we will be obligated to use commercially reasonable efforts to develop and commercialize products containing the monoclonal antibody in the United States and in at least one major European market.

If, after using commercially reasonable efforts to develop and commercialize products containing plasma-derived anti-HPA-1a immunoglobulin and the monoclonal antibody in the United States and in at least one major European market, we decide not to pursue any further development or commercialization activities for such products, then Prophylix will have the right to repurchase the remaining assets acquired under the agreement for approximately $1.2 million. Prophylix also will have the right to repurchase the remaining assets acquired under the agreement for approximately $1.2 million if we elect to transfer all or substantially all of the assets acquired under the agreement to a third-party who does not agree to assume our obligations to develop and commercialize the products.

Joint Venture Agreement

In July 2019, we entered into a partnership with Exscientia and created RE Ventures I, LLC, or RE Ventures, which is jointly owned by Exscientia and one of our wholly-owned subsidiaries. The joint venture was formed to initiate early-stage drug discovery of available small molecules targeting ENPP1 for the treatment of HPP, and thereafter for the future research, development, manufacture, sale and exploitation of any company-owned technology and compounds, including any resulting compound identified by the steering committee of the joint venture.

Under the RE Ventures operating agreement, we received a 50% interest in the joint venture in exchange for an initial contribution of £0.5 million ($0.6 million, based on the exchange rate at the time). RE Ventures used this initial capital to fund stage 1 of the ENPP1 program, and we committed to fund additional amounts if costs of stage 1 exceeded the initial funding. In June 2020, RE Ventures determined that the stage 1 objective of discovering compounds for ENPP1 with a certain potency had been achieved. In 2020, we contributed £1.1 million ($1.3 million, based on the exchange rate at the time) in support of ongoing Stage 2 development of the ENPP1 program.

In the event that either Member does not fund a portion of committed additional amounts, the other Member may contribute the unfunded amount and the respective membership interests in RE Ventures will be adjusted accordingly.

A steering committee is responsible for oversight of RE Ventures' research and deployment plans as well as intellectual property and regulatory matters. A two-person board of managers manages the business and affairs of RE Ventures and is responsible for all management and other responsibilities not specifically reserved to the steering committee or to the Members. Each Member designates one member to the board.

Each Member is subject to customary restrictions on its transfer of interests in RE Ventures, including a right of first refusal, co-sale right and drag-along provision.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any internal manufacturing facilities. We currently rely and expect to continue to rely on third-party contract manufacturer organizations, or CMOs, for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial production of any product candidates that are approved.

We currently rely on multiple CMOs for all of our preclinical and clinical supply requirements, including drug substances and drug products, and label and packaging for our preclinical research and clinical trials. We believe that we will be able to contract with other CMOs to manufacture drug substances if our existing sources of drug substances were no longer available to us or with sufficient capacity, but there is no assurance that the drug substance capacity would be available from other CMOs on acceptable terms, on the timeframe that our business would require, or at all. We do not currently have supply commitments or other arrangements in place with our existing CMOs.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved by the regulatory authorities, and we intend to enter into agreements with a CMO and one or more back-up manufacturers for the commercial production of our product candidates as they near phase 3 clinical trials.

Any products to be used in clinical trials and any approved product that we may commercialize will need to be manufactured in facilities, and by processes, that comply with the FDA's current Good Manufacturing Practice, or cGMP, requirements and comparable requirements of the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our CMOs.

We believe that RLYB212, RLYB116 and RLYB114 can be manufactured in reliable and reproducible biologic and chemical processes from readily available starting materials. We also believe that, despite being derived from human plasma, RLYB211 can also be manufactured in a reliable process, although our ability to source a sustained, dependable long-term supply will be challenging, including due to the scarcity of potential donors who maintain an adequate level of anti-HPA-1a antibodies and because supply of plasma will decrease if RLYB211 becomes clinically successful in preventing FNAIT. We believe that our manufacturing processes are amenable to scale-up and will not require unusual or expensive equipment. We expect to continue to develop, on our own or with our collaborators, product candidates that can be produced cost-effectively at contract manufacturing facilities.

We expect to rely on third parties for the manufacture of any in vitro diagnostic device, companion diagnostics or companion drug delivery systems we develop. For example, we have engaged a third-party to assist in developing laboratory screening tests and in our evaluation of potential companion diagnostics in conjunction with our development of RLYB212. Depending on the regulatory pathway and technology solutions we choose, we may engage third parties to continue the development and manufacturing of any device developed to support our therapeutic products.

Government Regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, pricing and reimbursement of drug and biologic products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biologics, also under the Public Health Service Act, or the PHSA, and their implementing regulations. Failure to comply with the applicable U.S. requirements may result in FDA refusal to approve pending NDAs or BLAs or delays in development and may subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or civil or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

The FDA must approve our product candidates for therapeutic indications before they may be marketed in the United States. For drug products, the FDA must approve a NDA, and for biologic products, the FDA must approve a BLA. An applicant seeking approval to market and distribute a new drug or biologic in the United States generally must satisfactorily complete each of the following steps:

- completion of preclinical laboratory tests and animal studies according to good laboratory practices, or GLP, regulations or other applicable regulations;
- manufacture and testing of the therapeutic or biologic moiety and its respective product formulation according to good manufacturing practices, or cGMP, regulations or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an independent institutional review board, or IRB, or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;
- review of the NDA or BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug or biologic and its respective finished product is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the NDA or BLA; and

- FDA review and approval of the NDA or BLA, which may be subject to additional post- approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS and any other potential post- approval studies required by the FDA.

Preclinical Studies and IND

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry/biology, formulation, and stability, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety and toxicology studies. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Imposition of a clinical hold could cause significant delays or difficulties in initiating and/or completing planned clinical trials in a timely manner. Certain long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may initiate or continue after an IND for an investigational product candidate is submitted to the FDA and human clinical trials have been initiated.

Human Clinical Trials in Support of an NDA or BLA

Clinical trials involve the administration of an investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, inclusion and exclusion criteria, dosing procedures and the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol, as well as any subsequent amendments, must be submitted to the FDA as part of the IND.

An IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review of the trial. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects or their legal representatives and must operate in compliance with FDA regulations.

Clinical trials must also comply with extensive GCP standards intended to ensure protection of human subjects and the quality and integrity of the study data, including requirements for obtaining subjects' informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the trial as planned, changes in trial conduct or cessation of the trial at designated checkpoints based on access to certain data from the study. The FDA may at any time while clinical trials are ongoing impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would cause suspension of an ongoing trial until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed.

Human clinical trials to evaluate therapeutic indications to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, and if possible, to gain early evidence for effectiveness. Phase 1 trials may be conducted in healthy volunteers or, in the case of some products for severe or life-threatening diseases, including many rare diseases, the initial human testing is often conducted in patients with the target disease or condition.

- Phase 2: Clinical trials are conducted in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: Clinical trials are undertaken with an expanded patient population to further evaluate dosage, and to provide substantial evidence of clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, to document a clinical benefit in the case of drugs or biologics approved under FDA's accelerated approval regulations and to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for the product.

The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Similar requirements for posting clinical trial information in clinical trial registries exist in the EU and in other countries outside the United States.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2 and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. For biological products in particular, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined in order to help ensure safety, purity and potency.

Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and FDA Review

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls (CMC) and proposed labeling, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support

marketing approval, the data submitted must be sufficient in quality to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act, or PDUFA, is substantial (for example, for FY2021 this application fee is approximately $2.9 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $300,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances. No user fee is required for orphan drug product applications, except when an application also includes an indication for a non-rare disease or condition.

The FDA conducts a preliminary review of all NDAs and BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an NDA or BLA to extend beyond the PDUFA goal date.

Before approving a NDA or BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the therapeutic/biologic to determine whether the manufacturing processes and facilities comply with GMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer any NDA or BLA, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA also may require submission of a REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS and the FDA will not approve the NDA or BLA without a REMS.

Under the Pediatric Research Equity Act of 2003, or PREA, an NDA or BLA or certain supplements thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless this requirement is waived, deferred or inapplicable. Sponsors must submit a pediatric study plan to FDA outlining the proposed pediatric study or studies they plan to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The FDA must then review the information submitted, consult with the sponsor and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. In general, PREA requirements do not apply to drugs or biologics for indications granted orphan drug designation by the FDA.

The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may

issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Regulation of Combination Products

Certain products may be comprised of components, such as drug or biologic components and device components that would normally be regulated under different types of regulations, and frequently by different centers at the FDA. These products are known as combination products. We expect to rely on a delivery system, such as pre-filled syringes, pen-injectors and/or autoinjectors to deliver certain of our product candidates. Although we have not yet selected the delivery system to use for administration of such product candidates, including RLYB212 and RLYB116, we expect that, if approved, any such product candidate would be regulated as a combination product, because it is composed of both a drug or biological product and a delivery system "device."

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although the lead center may consult with other centers within the FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for review of the drug product would have primary jurisdiction for the combination product.

A combination product involving a novel drug or biological product and delivery system generally would have a drug or biologic primary mode of action. A combination product with a drug or biologic primary mode of action would be reviewed and approved pursuant to the drug or biologic approval processes. In reviewing the NDA or BLA for such a product, however, the FDA review division reviewing the application could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Approval may require the performance of certain clinical studies, such as clinical usability or human factors studies to demonstrate the safety and/or effectiveness of the device component of the combination product.

Similar considerations apply to regulation of drugs combined with delivery systems outside the United States, including in the EU.

Expedited Programs for Serious Conditions

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation, priority review designation and accelerated approval.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA also may review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. Fast track designation may be rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy designation if it is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1 and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate. Breakthrough designation may be rescinded by the FDA if the designation is no longer supported.

The FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug or biologic qualifies for priority review. Significant improvement over available therapies may be illustrated, for example, by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or NDA from the date of filing.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Finally, the FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs granted accelerated approval, FDA generally requires sponsors to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless FDA informs the applicant otherwise.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, governing, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that drug and biological products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. In addition, for any of our product candidates that include a device delivery system, the device component will be subject to aspects of the Quality System Regulations, or QSRs, applicable to medical devices. Manufacturers of drug-device combination products may either opt to comply with all quality regulations governing each component of the product separately, or may take a "streamlined approach" to cGMP that allows the manufacturer to demonstrate compliance with the drug cGMPs along with compliance with several specific provisions from the device QSR—namely, management responsibility, design controls, purchasing controls, corrective and preventive action, installation, and servicing, as applicable.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations, including requirements for quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including voluntary recall and regulatory sanctions as described below.

Once an approval of a drug/biologic product is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market clinical trials

requirement to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, untitled letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Additionally, the Drug Supply Chain Security Act, or DSCSA, imposes requirements related to identifying and tracing certain prescription drugs distributed in the United States, including most biological products.

United States Patent Term Restoration and Hatch-Waxman Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval for our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent for other conditions of use. Three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

In addition, both drugs and biologics can obtain pediatric exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Biosimilars and Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars. No interchangeable biosimilars, however, have been approved. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an application that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from analytical studies showing that the biosimilar product is highly similar to the reference product, data from animal studies (including toxicity) and data from one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for the treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain tax credits. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for that drug for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any

other applications to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior. Absent a showing of clinical superiority, the FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete orphan disease designation application. To qualify for orphan exclusivity, however, the drug must be clinically superior to the previously approved product that is the same drug for the same condition. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

RLYB211 and RLYB212 have each been granted orphan drug designation by the FDA for the prevention of FNAIT.

Rare Pediatric Disease Designation and Priority Review Vouchers

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act requiring the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of “rare pediatric diseases” by, upon initial approval of an application meeting certain specified criteria, providing companies with a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

In order to receive a rare pediatric disease priority review voucher upon BLA or NDA approval, the product must receive designation from the FDA as a drug for a rare pediatric disease prior to submission of the marketing application. A “rare pediatric disease” is a disease that is serious or life-threatening, in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States, or affects more than 200,000 people in the United States but there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. In addition to receiving rare pediatric disease designation, in order to receive a rare pediatric disease priority review voucher, the NDA or BLA must be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a drug that does not include a previously approved active ingredient. In addition, under current statutory sunset provisions, even if a marketing application meets all of these requirements, FDA may only award a voucher prior to September 30, 2026 and only if the approved product received rare pediatric disease drug product designation prior to September 30, 2024.

RLYB211 and RLYB212 have each been granted rare pediatric disease designation by the FDA.

FDA Approval or Clearance of Companion Diagnostics

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require *marketing clearance via 510(k) notification or approval via Premarket Approval (“PMA”) application from the FDA prior to commercial distribution.*

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs and biologics, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the therapeutic products and *in vitro* companion diagnostic devices on issues related to co-development of the products.

The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. PMA applications are subject to an application fee, which for fiscal year 2021 is $365,657.

A clinical trial is typically required for a PMA application and, in some cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's investigational device exemption, or IDE, regulation. The IDE regulations distinguish between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Many companion diagnostics are considered significant risk devices due to their role in diagnosing a disease or condition. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. In the United States, device manufacturers are also subject to FDA's medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, and FDA's correction and removal reporting regulations, which require that manufacturers report to the FDA corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality System Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member EU, before we may commence clinical trials or market products in those countries or areas.

The United Kingdom's, or the U.K., withdrawal from the EU took place on January 31, 2020. The EU and the U.K. reached an agreement on their new partnership in the Trade and Cooperation Agreement, or the Agreement, to be applied from January 1, 2021. The Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the EU and the U.K. will form

two separate markets governed by two distinct regulatory and legal regimes. As such, the Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the U.K. is no longer part of the single market. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, becomes responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the EU.

With the exception of the EU/EEA applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union Drug Development, Review and Approval

In the EU, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the EU. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an IMPD (investigational medicinal product dossier principally based on the Common Technical Document developed by the International Council for Harmonization) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents issued by the European Commission and European Medicines Agency. All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the competent national authority and the Ethics Committee of the Member State where the clinical trial takes place.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or the Clinical Trials Regulation, was adopted and it is anticipated to come into application in late 2021 but could be delayed, subject to the full functionality of the Clinical Trials Information System (CTIS) through an independent audit. The Clinical Trials Regulation will come into application in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable.

The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation will come into application and on the duration of the individual clinical trial. According to the transitional provisions, if a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical

trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

For any of our product candidates that incorporate a medical device to administer the medicinal product and are intended to be commercialized as a single integral product intended exclusively for use in the given combination and not usable separately, then the combination product is regulated by Directive 2001/83/EC or Regulation (EC) 726/2004 as a medicinal product. However, the medical device used for administration must satisfy the requirements for its general safety and performance under EU law governing general medical devices.

The EU regulatory regime currently provided under Directive 93/42/EEC, or the Medical Devices Directive, will be replaced by Regulation (EU) 2017/745 on medical devices, or the Medical Devices Regulation. The Medical Devices Regulation will come into application on May 26, 2021, subject to the transitional provisions for certain medical devices to remain on the EU market if they were certified under the Medical Devices Directive for a limited period. There are significant changes to the EU regulatory system governing medical devices under the Medical Devices Regulation.

Under the Medical Devices Regulation, data relating to the general safety and performance of the medical device must be contained in an application for marketing authorization for the combination product. Such information must be provided by the manufacturer of the medical device in its EU declaration of conformity or the relevant certificate issued by a notified body allowing the medical device manufacturer to affix a European Conformity (“CE”) mark to the medical device. If the dossier submitted to support the marketing authorization does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with the Medical Devices Regulation, the medicinal products authority such as the EMA can require the applicant for a marketing authorization to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements issued by a designated notified body.

Marketing authorization applications, or MAA, can be filed either under the so-called centralized or national authorization procedures, albeit through the Mutual Recognition or Decentralized procedure for a product to be authorized in more than one EU member state.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency, or EMA, that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway, which are part of the EEA. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/ AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for medicinal products that fall outside the scope of the centralized procedure:

- ***Decentralized procedure***. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The applicant may choose a member state as the reference member State to lead the scientific evaluation of the application.
- ***Mutual recognition procedure***. In the mutual recognition procedure, a medicine is first authorized in one EU Member State (which acts as the reference member state), in accordance with the national procedures of that country. Following this, further marketing authorizations can be progressively sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization produced by the reference member state.

Under the above-described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Conditional Marketing Authorization

In specific circumstances, E.U. legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the drug candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population.

The EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP. This compliance check requirement applies to (a) a marketing authorization application based on a full stand-alone

dossier provided under Article 8(3) of Directive 2001/83/EC and (b) an application for variation or line-extension for a new pharmaceutical form or a new indication where the product is protected by a subsisting supplementary protection certificate (a form of patent extension under EU law) or a patent that qualifies for grant of a supplementary protection certificate.

European Union Regulatory Data Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term ‘significant benefit’ is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

RLYB211 and RLYB212 have each been granted orphan drug designation by the EMA for the prevention of FNAIT.

PRIME Designation

The EMA grants access to the Priority Medicines, or PRIME, program to investigational medicines for which it determines there to be preliminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner. Rallybio anticipates that it will request PRIME designation for certain of our product candidates.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Coverage, Pricing and Reimbursement

Sales of any biopharmaceutical products, if and when approved by the FDA or analogous authorities outside the United States, will depend in significant part on the availability of third-party coverage and reimbursement for the products.

In the United States, third-party payors include government healthcare programs such as Medicare and Medicaid, private health insurers, managed care plans and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including biopharmaceutical products. Significant uncertainty exists regarding coverage and reimbursement for newly approved healthcare products. Coverage does not ensure reimbursement. It is time consuming and expensive to seek coverage and reimbursement from third-party payors. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA regulatory approvals. Third-party payors may take into account clinical practice guidelines in determining coverage and there may be significant delays before our products are addressed by such guidelines and we cannot predict what position such guidelines would take with respect to our products if and when addressed. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, or utilize other mechanisms to manage utilization (such as requiring prior authorization for coverage for a product for use in a particular patient). Limits on coverage may impact demand for our products. Even if coverage is obtained, third-party reimbursement may not be adequate to allow us to sell our products on a competitive and profitable basis. As result, we may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, subject to the requirements set out in Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, EU Member States have the legal competence to set national measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products. Accordingly, EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel import or distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. Health Care Laws and Regulations

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which will apply only if and when we have an approved product, include:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- laws and regulations prohibiting bribery and corruption, such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly.

Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Health Care Reform in the United States and Potential Changes to Health Care Laws

Health care reform has been a significant trend in the U.S. health care industry and elsewhere. In particular, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services. Under the Trump administration, there were efforts to repeal or modify prior health care reform legislation and regulation and to implement new health care reform measures, including measures related to payment for drugs under government health care programs. The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain but early actions include additional health care reform as well as challenges to actions taken under the Trump administration are likely.

There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical and biologic products. At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Data Privacy Regulation

U.S. Privacy Law

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including laws requiring the safeguarding of personal information and laws requiring notification to governmental authorities and data subjects as well as remediation in the event of a data breach.

There have been several developments in recent years with respect to U.S. state data privacy laws. In 2018, California passed into law the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. On November 3, 2020, California voters passed a ballot initiative for the CPRA, which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022. Similar laws have been proposed or passed at the U.S. federal and state level, including the Virginia Consumer Data Protection Act, which will take effect on January 1, 2023.

General data protection regulation (GDPR)

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million, or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR.

Employees and Human Capital Resources

Our employees are driven by our mission to identify and accelerate the development of transformative therapies for patients with rare disorders. We believe that our deep commitment to high ethical and professional standards is fundamental to our mission, and we are determined to build a culture that values diversity, inclusiveness and equity, and empowers a skilled and experienced workforce to perform at the highest levels. We commit our resources and

make investments, including through recruiting, training and collaboration, to promote the culture that we desire, and we expect our employees to embrace the company's values and culture in all that we do.

As of March 31, 2021, we employed 22 full-time employees. Of our full-time employees, 13 employees are engaged in new product sourcing through business development, research, manufacturing, product development and clinical development, and 9 are engaged in finance, human resources, legal and other administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based incentive awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We offer a benefits program that provides resources to help employees manage their health, finances and life outside of work.

Facilities

Our corporate headquarters is located at 234 Church Street, Suite 1020, New Haven, CT 06510, where we lease and occupy 4,500 square feet of office space. The current term of our New Haven lease expires May 31, 2025. We also lease 117 square feet of office space at 400 Farmington Avenue, Suite R2846, Farmington, CT 06032. The current term of our Farmington lease expires January 31, 2022.

We believe our existing facilities are sufficient for our current needs. To meet the future needs of our business, we expect to lease additional or alternate office space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

MANAGEMENT

Executive Officers and Directors

Our executive officers and directors, their ages as of March 31, 2021, and their positions, are as set forth below:

NAME	AGE	POSITION(S)
Executive Officers		
Martin W. Mackay, Ph.D.	64	Chief Executive Officer and Chairman
Stephen Uden, M.D.	63	President, Chief Operating Officer and Chief Scientific Officer
Jeffrey M. Fryer, CPA	51	Chief Financial Officer and Treasurer
Steven Ryder, M.D.	70	Chief Medical Officer
Non-Management Directors		
Helen M. Boudreau	55	Director
Rob Hopfner, R.Ph., Ph.D.	48	Director
Ronald M. Hunt	56	Director
Lucian Iancovici, M.D.	38	Director
Kush M. Parmar, M.D., Ph.D.	40	Director
Timothy M. Shannon, M.D.	62	Director
Paula Soteropoulos	53	Director

Executive Officers

Martin W. Mackay, Ph.D., is a co-founder of, and has been Chief Executive Officer and Chairman of the board of directors of, Rallybio since January 2018. From March 2013 to December 2017, Dr. Mackay served as the Executive Vice President and Global Head of Research & Development at Alexion Pharmaceuticals, Inc., or Alexion, and, from July 2010 to January 2013, Dr. Mackay served as the President of Research & Development at AstraZeneca PLC. Prior to AstraZeneca, Dr. Mackay worked at Pfizer, Inc., or Pfizer, for 15 years where he held positions of increasing responsibility, including president, head of pharmatherapeutics research and development. Dr. Mackay currently serves on the board of directors of 5:01 Acquisition Corp, Charles River Laboratories International, Inc., and Novo Nordisk A/S. Dr. Mackay earned a BSc First Class in microbiology from Heriot-Watt University and a Ph.D. in molecular genetics from the University of Edinburgh. Dr. Mackay's extensive experience serving on other boards and leading research and development organizations at both global pharmaceutical and biotechnology companies provides our board of directors with a unique combination of expertise.

Stephen Uden, M.D., is a co-founder of, and has been President, Chief Operating Officer and Chief Scientific Officer of Rallybio since January 2018. Previously, Dr. Uden served as Senior Vice President, Research at Alexion from June 2014 to October 2017. Prior to Alexion, Dr. Uden served in various leadership roles in the research organizations of Novartis (Japan), Wyeth (Japan), Neurogen and Pfizer. Dr. Uden earned a BSc in biochemistry and an M.B., B.S. in medicine from the University of London.

Jeffrey M. Fryer**, CPA,** is a co-founder of, and has been Chief Financial Officer and Treasurer of, Rallybio since January 2018. Previously, Mr. Fryer served as Vice-President and Chief Tax Officer of Alexion from April 2008 to April 2017. Prior to Alexion, Mr. Fryer lead the corporate tax functions at Chemtura Corporation and Lydall, Inc., and served for over ten years with PwC as a senior tax manager. He earned an M.S. in taxation from the University of Hartford and a B.S. in business administration with a concentration in accounting from Bryant University. Mr. Fryer is a member of the Dean's Advisory Council for the Bryant University School of Business.

Steven Ryder, M.D., has been Chief Medical Officer of Rallybio since January 2019. Previously, Dr. Ryder served as Chief Development Officer at Alexion from July 2013 to December 2018. From April 2008 to April 2013, Dr. Ryder served as President of Astellas Pharma Global Development at Astellas Inc, or Astellas. Prior to joining Astellas, Dr. Ryder worked at Pfizer for 21 years where he held positions of increasing responsibility, including head of worldwide clinical development. Dr. Ryder earned an M.D. from the Icahn School of Medicine at Mount Sinai.

Non-employee Directors

Helen M. Boudreau has served as a member of our board of directors since September 2020. From June 2018 to June 2019, Ms. Boudreau served as Chief Operating Officer of the Bill & Melinda Gates Medical Research Institute, a non-profit biotech. Previously, she served as Chief Financial Officer from July 2017 to June 2018 and as a board member from February 2016 to July 2017 of Proteostasis Therapeutics, Inc. From October 2014 to June 2017, Ms. Boudreau served as Chief Financial Officer of FORMA Therapeutics, Inc., and from September 2008 to September 2014, Ms. Boudreau served in senior finance roles at Novartis AG, including Chief Financial Officer Novartis Corporation US and Chief Financial Officer Global Oncology. Prior to Novartis, Ms. Boudreau served in roles of increasing responsibility in strategy and finance at Pfizer Inc. from April 1999 to September 2008, including Vice President Finance Customer Business Unit and Commercial Operations and Vice President Finance, Pfizer Global Research and Development. Ms. Boudreau worked earlier in her career at PepsiCo Inc. and YUM! Brands, Inc., McKinsey & Company and Bank of America Corporation. Ms. Boudreau currently serves as a board member of Evaxion Biotech A/S, Field Trip Health Ltd., Premier, Inc. and Shattuck Labs Inc. Ms. Boudreau previously served on the board of directors of Proteostasis Therapeutics, Inc. Ms. Boudreau earned a B.A. in Economics from the University of Maryland, where she graduated *summa cum laude*, and an M.B.A. from the Darden Graduate School of Business at the University of Virginia. We believe Ms. Boudreau is qualified to serve on our board of directors because of her financial expertise and extensive experience as an executive and director with biotechnology companies.

Rob Hopfner, R.Ph., Ph.D, has served as a member of our board of directors since March 2020. Since October 2017, Dr. Hopfner has served as a Managing Partner at Pivotal bioVenture Partners LLC, a venture capital firm. Prior to Pivotal, Dr. Hopfner served as a Principal at Bay City Capital LLC, a venture capital firm, from June 2007 to October 2009 and as a Managing Director and Partner from October 2009 to September 2017. Dr. Hopfner currently serves as a board member of Vaxcyte, Inc. and Inozyme Pharma, Inc., and on the boards of a number of private life sciences companies. Dr. Hopfner earned a B.Sc. in Pharmacy and a Ph.D. in Pharmacology from the University of Saskatchewan and an M.B.A. from the University of Chicago. We believe Dr. Hopfner is qualified to serve on our board of directors because of his experience in advising public and private life sciences companies, as well as his research in the pharmaceutical field.

Ronald M. Hunt has served as a member of our board of directors since March 2019. Since 2005, Mr. Hunt has served as a Managing Director and Member of New Leaf Venture Partners, L.L.C., a venture capital firm. Previously, Mr. Hunt served at the Sprout Group, a venture capital firm and was a consultant with consulting firms Coopers & Lybrand Consulting and The Health Care Group, Inc. Mr. Hunt worked earlier in his career in various sales and marketing positions at Johnson & Johnson and SmithKline Beecham Pharmaceuticals PLC. Mr. Hunt currently serves as a board member of Harpoon Therapeutics, Inc. and Iterum Therapeutics, Ltd., a clinical-stage therapeutics company, and on the boards of a number of private pharmaceutical and healthcare companies. Mr. Hunt previously served on the board of directors of Neuronetics, Inc. Mr. Hunt earned a B.S. from Cornell University and an M.B.A. from the Wharton School of the University of Pennsylvania. We believe Mr. Hunt is qualified to serve on our board of directors because of his investment experience, his experience in the pharmaceutical industry and service on the boards of other public and private biopharmaceutical and biotechnology companies.

Lucian Iancovici, M.D., has served as a member of our board of directors since May 2020. Dr. Iancovici is currently a Managing Director of TPG Growth, where he has worked since January 2018. From September 2012 to October 2017, Dr. Iancovici served as the head of the Qualcomm Life Fund, a venture fund focused on investing in digital health technologies. From January 2015 to October 2017, Dr. Iancovici was a general partner at dRx Capital, a joint venture investment company launched by Novartis and Qualcomm. From 2011 to 2012, Dr. Iancovici was an associate at McKinsey & Company. Lucian is a board certified internal medicine doctor, who trained at Columbia University Medical Center in New York prior to joining McKinsey and Company. Dr. Iancovici earned his bachelor's degree in economics and an M.D., both from Tufts University. We believe that Dr. Iancovici is qualified to serve on our board of directors because of his extensive experience in the venture capital industry, and his medical and scientific background and training.

Kush M. Parmar, M.D., Ph.D., has served as a member of our board of directors since April 2018. Dr. Parmar is currently a Member of 5AM Venture Management, LLC, where he has worked since 2010. Dr. Parmar also serves as

Co-Chief Executive Officer and as member of the board of directors of 5:01 Acquisition Corp, positions he has held since its inception in September 2020. Dr. Parmar currently serves as a board member of Akouos, Inc., Entrada Therapeutics, Inc., Ensoma Inc., Homology Medicines, Inc. and Vor Biopharma Inc., and previously served on the board of directors of Arvinas, Inc., Audentes Therapeutics, Inc. and scPharmaceuticals, Inc. Dr. Parmar earned a B.A. in molecular biology and medieval studies from Princeton University, a Ph.D. in experimental pathology from Harvard University and an M.D. from Harvard Medical School. We believe that Dr. Parmar is qualified to serve on our board of directors because of his extensive experience in the venture capital industry, medical and scientific background and training, and service on the boards of other public and private biopharmaceutical and biotechnology companies.

Timothy M. Shannon, M.D., has served as a member of our board of directors since April 2018. Dr. Shannon has been both a Non-Managing Member of Canaan Partners IX LLC, a Managing Member of Canaan Partners X LLC, a Managing Member of Canaan Partners XI LLC, and a Managing Member of Canaan Partners XII LLC, all entities affiliated with Canaan Partners, a venture capital firm, since November 2009. While at Canaan, Dr. Shannon served in a number of executive roles at biotechnology companies, including as President and Chief Executive Officer of Aldea Pharmaceuticals, Inc. and of Arvinas, Inc. Prior to Canaan, Dr . Shannon served as Executive Vice President of R&D and Chief Medical Officer of Curagen Corporation and Senior Vice President of Global Medical Development, Bayer Healthcare LLC. Dr. Shannon currently serves as chairman of the board of directors of Arvinas, Inc. and of Ideaya Biosciences, Inc., as well as several privately held companies. Dr. Shannon previously served as a board member of NextCure Inc., and CytomX Therapeutics, Inc. Dr. Shannon earned a B.A. in chemistry from Amherst College and an M.D. from the University of Connecticut. We believe Dr. Shannon is qualified to serve on our board of directors because of his extensive experience in the venture capital industry, his executive leadership experience, his medical background and training, and his service on the boards of other public and private biopharmaceutical companies.

Paula Soteropoulos has served as a member of our board of directors since October 2020. Ms. Soteropoulos currently serves as the Executive Chairman of Ensoma, a private venture-backed company. She previously served as Chief Executive Officer and President of Akcea Therapeutics, Inc. from January 2015 to September 2019, where she was also a member of the board of directors. Prior to Akcea, Ms. Soteropoulos served as Senior Vice President and General Manager, Cardiometabolic Business and Strategic Alliances at Moderna Therapeutics Inc., and prior to Moderna, she served in various roles of increasing responsibility at Genzyme Corporation, including as Vice President and General Manager, Cardiovascular, Rare Diseases. Ms. Soteropoulos currently serves on the board of directors of uniQure N.V. Ms. Soteropoulos also serves as a Strategic Advisor to 5AM Venture Management, LLC. Ms. Soteropoulos earned both a B.S. in chemical and biochemical engineering and an M.S. in chemical and biochemical engineering from Tufts University, and holds an executive management certificate from the Darden Graduate School of Business at the University of Virginia. Ms. Soteropoulos serves on the Advisory Board for the Chemical and Biological Engineering Department of Tufts University. We believe Ms. Soteropoulos is qualified to serve on our board of directors because of her extensive experience in the biotechnology industry, her executive leadership experience and her service on the boards of other public and private biopharmaceutical companies.

Board Composition and Election of Directors

Our board of managers currently consists of eight members, all of whom were elected as managers pursuant to our Operating Agreement. The Operating Agreement will terminate prior to the consummation of this offering and there will be no further contractual obligations regarding the election of our directors. Following the Reorganization, the board of directors of Rallybio Corporation, or the Corporation, will consist of the same eight members who will be duly elected in accordance with the bylaws of the Corporation. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

There are no family relationships among any of our directors and executive officers.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, which will be in effect prior to the consummation of this offering, our board of directors will be divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms

are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal. Upon the closing of this offering, our directors will be divided among the three classes as follows:

The Class I directors will be , and their terms will expire at our 2022 annual meeting of stockholders.

The Class II directors will be , and their terms will expire at our 2023 annual meeting of stockholders.

The Class III directors will be , and their terms will expire at our 2024 annual meeting of stockholders.

Our amended and restated certificate of incorporation for the Corporation will provide that the authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus captioned “Description of Capital Stock—Anti-takeover Effects of Our Amended and Restated Certificate of Incorporation and Bylaws” for a discussion of these and other anti-takeover provisions found in our amended and restated certificate of incorporation and amended and restated bylaws, which will be in effect prior to the consummation of this offering.

Director Independence

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company’s board of directors within one year of the completion of its initial public offering. In addition, the rules of the Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company’s audit and compensation committees be independent and that director nominees be selected or recommended for the board’s selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the rules of the Nasdaq Stock Market, a director will only qualify as “independent” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is “independent” as defined under the rules of the Nasdaq Stock Market and the rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Martin W. Mackay , is an “independent director” as defined under applicable rules of the Nasdaq Stock Market, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act and are “non-employee directors” as defined in Section 16b-3 of the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Dr. Martin W. Mackay is not an independent director under these rules because he is our Chief Executive Officer.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors that will become effective prior to the consummation of this offering. Our board of directors may also establish other committees from time to time to assist us and the board of directors in their duties. Upon the effectiveness of the

registration statement of which this prospectus forms a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, the Nasdaq Stock Market and the Exchange Act. Upon our listing on the Nasdaq Global Market, each committee's charter will be available on the corporate governance section of our website at www.rallybio.com. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

Audit Committee

The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance and independence of, our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations;
- reviewing disclosures about any significant deficiencies or material weaknesses in our internal controls, including disclosures in our annual and quarterly reports;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee are . chairs the audit committee. Our board of directors has determined that each member of our audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined that is an "audit committee financial expert," as defined under Item 407 of Regulation S-K.

We expect to satisfy the member independence requirements for the audit committee prior to the end of the transition period provided under the rules of the Nasdaq Stock Market and SEC rules and regulations for companies completing their initial public offering.

Compensation Committee

Our compensation committee's responsibilities upon completion of this offering will include:

- reviewing our overall management compensation strategy, including base salary, incentive compensation and equity-based grants;

- reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and other executive officers;
- recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors with respect to non-employee director compensation;
- overseeing and administering our cash and equity incentive plans;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and non-employee directors;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual report on Form 10-K and our annual proxy statement in accordance with SEC proxy and disclosure rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- establishing and periodically reviewing policies and procedures with respect to perquisites as they relate to our executive officers;
- reviewing the risks associated with our compensation policies and practices;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions based on guidelines developed and recommended to the compensation committee to the full board of directors;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are . chairs the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our stockholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principles applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility;
- making recommendations to our board of directors processes for annual evaluations of the performance of our board of directors and committees of our board of directors;

- overseeing the process for annual evaluations of our board of directors and committees of our board of directors;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- reviewing with management the company's social corporate responsibility activities, policies, and program;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the Company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are . chairs the nominating and corporate governance committee. Our board of directors has determined that each member of the nominating and corporate governance committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market.

Our board of directors may establish other committees from time to time.

Role of the Board in Risk Oversight

Our board of directors has, and, upon the completion of this offering, its committees will also have, an active role in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee will be responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and governance committee will be responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee will be responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors will be regularly informed through discussions from committee members about such risks.

Code of Business Conduct and Ethics

Prior to the closing of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part. Following this offering, a current copy of the code will be posted on the investor section of our website. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq Stock Market rules concerning any amendments to, or waivers from, any provision of the code.

EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion and analysis of compensation arrangements should be read with the compensation tables and related disclosures set forth below. This discussion contains forward looking statements that are based on our current plans and expectations regarding future compensation programs. The compensation programs that we adopt in the future may differ materially from the programs summarized in this discussion.

Introduction

This section provides an overview of the compensation awarded to, earned by, or paid to our principal executive officer and our next two most highly compensated executive officers listed below in respect of their service to us for the fiscal year ended December 31, 2020. We refer to these individuals as our named executive officers. Our named executive officers are:

- Martin W. Mackay, Ph.D., Chief Executive Officer and Chairman;
- Stephen Uden, M.D., President, Chief Operating Officer and Chief Scientific Officer; and
- Jeffrey M. Fryer, Chief Financial Officer and Treasurer.

Prior to this offering, the board of managers of Rallybio Holdings, LLC, or the LLC Entity (referred to as our board of managers for purposes of this executive and director compensation discussion), was responsible for determining the compensation of our executive officers, based on recommendations from the compensation committee of the board of managers. Following this offering, the compensation committee of the board of directors of Rallybio Corporation, or the Corporation, will be responsible for making such determinations. Drs. Mackay and Uden, and Mr. Fryer are our founders and, since our inception, have received identical compensation. Following this offering, the compensation committee may make similar recommendations regarding the compensation payable to the founders.

Summary compensation table

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to us for the fiscal year ended December 31, 2020:

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	STOCK AWARDS ($) [1]	NONEQUITY INCENTIVE PLAN COMPENSATION ($) [2]	ALL OTHER COMPENSATION ($) [3]	TOTAL ($)
Martin W. Mackay, Ph.D.	2020	379,500	292,600	151,800	14,156	838,056
Chief Executive Officer and Chairman						
Stephen Uden, M.D.	2020	379,500	292,600	151,800	14,156	838,056
President, Chief Operating Officer and Chief Scientific Officer						
Jeffrey M. Fryer, CPA	2020	379,500	292,600	151,800	14,156	838,056
Chief Financial Officer and Treasurer						

(1) The amounts shown in this column represent the grant date fair value of incentive units granted to Drs. Mackay and Uden and Mr. Fryer in fiscal year 2020 computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the incentive units for this purpose are set forth in Note 7 to our consolidated financial statements included elsewhere in this prospectus.

(2) The amounts shown in this column represent annual bonuses earned with respect to fiscal year 2020 that were paid in February 2021 under our annual bonus program as described below under “Annual Bonuses.”

(3) The amounts shown in the “All Other Compensation” column reflect SIMPLE IRA matching contributions made by the LLC Entity, described below under “Employee and Retirement Benefits.”

Narrative disclosure to summary compensation table

Agreements with our named executive officers

Drs. Mackay and Uden and Mr. Fryer are each party to an employment agreement with our operating company subsidiary, Rallybio, LLC, which sets forth the terms and conditions of the executive officer's employment with us. The material terms of the agreements are described below. The terms "cause" and "good reason" referred to below are defined in the respective named executive officer's agreement.

Each employment agreement provides for an initial annual base salary, subject to review for increase by our board of managers or a committee of our board of managers, which base salary has since been increased by our board of managers. Each employment agreement also provides for a target annual bonus equal to 40% of annual base salary, with the actual amount of the bonus payable based upon the achievement of performance goals as determined by our board of managers or a committee of our board of managers.

Annual base salary

The employment agreement with each named executive officer establishes an annual base salary for the executive officer, which was determined at the time that the named executive officer commenced employment with us and is subject to periodic review. Effective January 1, 2020, the annual base salaries of Drs. Mackay and Uden and Mr. Fryer were increased from $370,000 to $379,500. Effective January 1, 2021, the annual base salaries of our named executive officers were increased to $420,000.

Annual bonuses

With respect to fiscal year 2020, each of Drs. Mackay and Uden and Mr. Fryer was eligible to receive an annual bonus, with the target amount of such bonus for each named executive officer set forth in his employment agreement with us. For fiscal year 2020, the target bonus amount, expressed as a percentage of annual base salary, for each of Drs. Mackay and Uden and Mr. Fryer was 40%. Annual bonuses for fiscal year 2020 for our named executive officers were based on the attainment of pre-established corporate objectives as determined by our board of managers, including those related to building a world-class team, business development, expanding the LLC Entity's pipeline, financing, and developmental and clinical goals. Following the end of fiscal year 2020, our board of managers determined that the performance goals were met at target and each of Drs. Mackay and Uden and Mr. Fryer earned a bonus of $151,800.

Severance upon termination of employment; change of control; restrictive covenants.

Employment Agreements. Each of Drs. Mackay and Uden and Mr. Fryer is entitled to severance payments and benefits in connection with certain qualifying terminations of employment under his respective employment agreement. If the executive officer's employment is terminated by us without cause, as a result of our non-extension of the employment term or by him for good reason, he will be entitled to receive (i) any earned and payable, but unpaid, prior year annual bonus (or current year bonus if the termination is on the last day of the calendar year) and (ii) continued payment of his annual base salary for a period of six months following termination (or payment of a lump sum amount equal to six months' annual base salary, if the termination of employment is in connection with a sale of the company). If the executive officer's employment is terminated by reason of his death or disability, he will be entitled to receive (i) any earned and payable, but unpaid, annual bonus and (ii) continued payment of his annual base salary for a period of six months following termination.

Severance Subject to Release of Claims. Our obligation to provide a named executive officer with severance payments and other benefits under his respective employment agreement is conditioned on the executive officer signing a release of claims in favor of us.

Restrictive Covenants. Under their respective employment agreements, each of Drs. Mackay and Uden and Mr. Fryer has agreed not to compete with us during his employment and for one year following his termination of employment or solicit our customers, employees, representatives, agents, vendors, joint venturers or licensors during his employment and for one year following his termination of employment. In addition, each named executive officer has agreed to a perpetual non-disparagement covenant.

Equity. Upon a change of control (as defined in each named executive officer's award agreement or the Rallybio Holdings, LLC 2018 Share Plan, or the 2018 Plan), each named executive officer's restricted common units granted

to him on April 19, 2018 that have not vested will vest, and the proceeds to be received in connection with such change of control in respect of such accelerated units will be held in escrow to be released on the one-year anniversary of the change of control, subject to forfeiture if the named executive officer's employment is terminated by us with cause or by him for good reason prior to such date. The escrow funds will be released immediately if the named executive officer's employment is terminated by us without cause or by him for good reason during such one-year period.

Equity compensation

Drs. Mackay and Uden and Mr. Fryer received incentive equity grants in fiscal year 2020 under the 2018 Plan.

On July 31, 2020, each of Drs. Mackay and Uden and Mr. Fryer was granted an award of 665,000 incentive units, which vest as to 25% of the underlying units on April 1, 2021 and in 36 equal monthly installments thereafter, generally subject to the executive officer's continued employment with us through the applicable vesting date.

In January 2021, each of our named executive officers received an award of 2,255,000 incentive units under the 2018 Plan, which vest as to 25% of the underlying units on January 1, 2022 and in 36 equal monthly installments thereafter, generally subject to the executive officer's continued employment with us through the applicable vesting date.

Employee and retirement benefits

We currently provide broad-based health and welfare benefits that are available to all of our employees, including our named executive officers, including health, life and AD&D, disability, vision, and dental insurance. In addition, we maintain a SIMPLE IRA retirement plan for our full-time employees. The SIMPLE IRA plan provides that we will make matching employer contributions to the SIMPLE IRA plan equal to up to 3% of eligible compensation contributed to the plan by an eligible employee for the applicable year (subject to tax code limits). Other than the SIMPLE IRA plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named executive officers.

Outstanding awards at fiscal year-end 2020

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2020:

	STOCK AWARDS	
NAME	NUMBER OF UNITS THAT HAVE NOT VESTED (#)	MARKET VALUE OF UNITS THAT HAVE NOT VESTED ($) (1)
Martin W. Mackay, Ph.D.	562,500 (2)	
	275,000 (3)	
	665,000 (4)	
Steve Uden, M.D.	562,500 (2)	
	275,000 (3)	
	665,000 (4)	
Jeffrey M. Fryer, CPA (5)	562,500 (2)	
	275,000 (3)	
	665,000 (4)	

(1) Because the LLC Entity was not publicly traded during fiscal year 2020, there is no ascertainable public market value for these units. The market value reported in this table is based upon our board of manager's determination of the fair market value of the LLC Entity's equity, $ per common unit, which was determined taking into account an independent valuation analysis performed in , the closest valuation date to fiscal year-end. Where applicable, the fair market value of an incentive unit included in this table reflects the value of a common unit less any unsatisfied distribution threshold.

(2) Represents an award of 1,499,999 restricted common units of the LLC Entity issued on April 19, 2018 pursuant to a contribution and restricted share agreement with each named executive officer, which vested as to 25% of the common units on the date of grant and as to the remaining common units in four equal installments on each of April 20, 2019, April 20, 2020, April 20, 2021 and April 20, 2022, generally subject to the executive officer's continued employment with us through the applicable vesting date.

(3) Represents an award of 400,000 restricted common units of the LLC Entity granted on April 19, 2018 under the 2018 Plan, which became eligible to vest upon the initiation of a clinical program through one of our affiliates, on September 12, 2019. Twenty-five percent of the underlying common units vested on September 12, 2020, and the remaining common units vest in 36 equal monthly installments thereafter, generally subject to the executive officer's continued employment with us through the applicable vesting date.

(4) Represents an award of 665,000 incentive units of the LLC Entity granted on July 31, 2020 under the 2018 Plan, which vest as to 25% of the underlying units on April 1, 2021 and vests in 36 equal monthly installments thereafter, generally subject to the executive officer's continued employment with us through the applicable vesting date.

(5) Mr. Fryer's grants are held by a revocable trust.

Director compensation

The following table sets forth the compensation awarded to, earned by or paid to our non-employee directors during the fiscal year ended December 31, 2020. Dr. Mackay does not receive compensation for his service as a director. His compensation for 2020 is included with that of our other named executive officers above.

NAME	FEES EARNED OR PAID IN CASH ($) (1)	STOCK AWARDS ($) (2)	TOTAL ($)
Helen M. Boudreau	13,152	85,295	98,447
Rob Hopfner, R.Ph., Ph.D. (3)	—	—	—
Ronald Hunt (3)	—	—	—
Lucian Iancovici, M.D. (3)	—	—	—
Kush M. Parmar, M.D., Ph.D. (3)	—	—	—
Ketan Patel, M.D. (3)(4)	—	—	—
Timothy M. Shannon, M.D. (3)	—	—	—
Paula Soteropoulos	5,992	85,295	91,287

(1) The amounts reported in this column represent cash fees earned in fiscal year 2020.

(2) The amounts reported in this column represent the grant date fair value of incentive units granted to Mses. Boudreau and Soteropoulos computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the incentive units for this purpose are set forth in Note 7 to our consolidated financial statements included elsewhere in this prospectus. As of December 31, 2020, Ms. Boudreau and Ms. Soteropoulos held 12,115 and 8,077 vested incentive units of the LLC Entity, respectively.

(3) Directors who are affiliated with our investors do not receive compensation in respect of their service as members of our board of managers.

(4) Dr. Patel resigned from our board of managers effective January 30, 2021.

Director compensation

At the time each of Ms. Boudreau and Ms. Soterpoulos was appointed to our board of managers, we agreed to pay each of them a cash retainer of $35,000 for board service and Ms. Boudreau a cash retainer of $5,000 for service as chair of the audit committee, and to provide each of them a grant of incentive units, as reported in the table above. The incentive units vest in 48 equal monthly installments, generally subject to the director's continued service through the applicable vesting date.

Director compensation policy

In connection with this offering, we expect to adopt a formal non-employee director compensation policy for members of our board of directors, the terms of which will be described in a subsequent filing.

Equity and cash plans

2018 Share Plan

In 2018, our board of managers approved the 2018 Plan. The 2018 Plan has been amended from time to time to increase the aggregate number of common units of the LLC Entity reserved for issuance under the 2018 Plan, and was most recently amended on January 20, 2021. The 2018 Plan permits the grant of options to purchase common units, restricted common units and other awards that are convertible into or otherwise based on common units. Subject to adjustment, the maximum number of common units that may be granted under the 2018 Plan is 22,972,360. As of , 2021, incentive units and restricted common units were outstanding

under the 2018 Plan and common units remained available for future issuance. It is anticipated that no further awards will be made under the 2018 Plan following the completion of this offering. In connection with this offering, we intend to adopt a new omnibus equity plan under which we will grant equity-based awards in connection with or following this offering. This summary is not a complete description of all provisions of the 2018 Plan and is qualified in its entirety by reference to the 2018 Plan, which is filed as an exhibit to the registration statement of which this prospectus is part.

Plan administration

Our board of managers administers the 2018 Plan. Our board of managers has the discretionary authority to grant awards, to construe award agreements and the 2018 Plan, to prescribe, amend and rescind rules and regulations relating to the 2018 Plan, to determine the terms and provisions of the award agreements and to make all other determinations in the judgment of our board of managers necessary or desirable for the administration of the 2018 Plan. Our board of managers may delegate any or all of its powers to a committee. As used in this summary, the term "Administrator" refers to our board of managers and its authorized delegates, as applicable.

Eligibility

Our and our affiliates' employees, officers, managers, directors, advisors and consultants are eligible to participate in the 2018 Plan.

Vesting; terms of awards

The Administrator determines the terms and conditions of all awards granted under the 2018 Plan, including the time or times an award vests or becomes exercisable, the terms on which an award remains exercisable. The Administrator may at any time accelerate the vesting or exercisability of an award.

Transferability of awards

Except as the Administrator may otherwise determine, options may not be transferred other than by will or by the laws of descent and distribution or pursuant to a qualified domestic relations order. Common units may not be transferred unless the transfer complies with all provision of the 2018 Plan and the operating agreement of the LLC Entity.

Effect of certain transactions

In the event of change of control, as defined in the 2018 Plan, the Administrator may, with respect to outstanding awards, provide for the acceleration of exercisability or issuance of common units in respect of any award, in full or in part or the cash-out of awards. If not accelerated or cashed out, the awards will be assumed or substituted by the successor company, and to the extent not assumed or substituted, any outstanding option will terminate and awards of common units will be repurchased.

Adjustment provisions

If, through or as a result of any recapitalization, reclassification, distribution, common unit split, reverse common unit split, liquidation, exchange of common units, spin-off, combination, consolidation or other similar transaction, (i) the outstanding common units are increased, decreased or exchanged for a different number or kind of common units or other securities or (ii) additional common units or new or different common units or other non-cash assets are distributed with respect to such common units or other securities, an appropriate and proportionate adjustment will be made to (x) the maximum number and kind of common units reserved for issuance under the 2018 Plan, (y) the number and kind of securities underlying awards then outstanding and (z) the exercise price for each option, without changing the aggregate purchase price as to which such options remain exercisable.

Amendments and termination

The Administrator may at any time amend the 2018 Plan and may at any time terminate the 2018 Plan as to future grants. However, except as expressly provided in the 2018 Plan, the Administrator may not alter the terms of the plan so as to adversely affect a participant's rights under an award without the participant's consent. Any amendments to the 2018 Plan will be conditioned on member approval to the extent required.

2021 Compensation plans

We expect that we will adopt a new equity incentive plan, an employee stock purchase plan and a new cash incentive plan in connection with this offering, the terms of which will be described in a subsequent filing.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 5, 2018, the date on which Rallybio, LLC was incorporated, to which we have been a party in which the amount involved exceeded the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus captioned “Executive and Director Compensation.”

2018 Reorganization

In January 2018, Drs. Mackay and Uden and Mr. Fryer, collectively the Founders, formed Rallybio, LLC. Each Founder made an initial capital contribution of $300 and each received 3,000,000 common units of Rallybio, LLC.

In March 2018, the Founders formed Rallybio Holdings, LLC, or the LLC Entity, each contributing $1 in exchange for 1 common unit in the LLC Entity. Subsequently, as part of a reorganization in April 2018, the Founders contributed all of their common units in Rallybio, LLC to the LLC Entity in exchange for common units of the LLC Entity. As a result of their contribution, the Founders were each issued 1,899,999 common units in the LLC Entity, of which 374,999 common units were vested immediately, 1,125,000 common units vest in four equal yearly installments on the anniversary date of the reorganization, and 400,000 common units would begin vesting upon achieving a clinical development milestone. In September 2019, this clinical development milestone was achieved and 25% of these common units vested on the one year anniversary of the date such milestone was achieved, and the remaining 75% vests in equal monthly increments over the next thirty-36 months until fully vested.

Private Placements

Series A-1 Preferred Units

In April 2018, we entered into a Series A Preferred Share Purchase Agreement to sell up to 5,999,999 units of Series A-1 Redeemable Convertible Preferred Units, or Series A-1 Units, to investors at a purchase price of $1.00 per unit, and up to 26,956,516 units of Series A-2 Redeemable Convertible Preferred Units, or Series A-2 Units, upon the Company’s achievement of certain milestone events, to investors at a purchase price of $1.15 per unit.

In April 2018, we completed the sale of 5,549,999 shares of our Series A-1 Units to investors at a purchase price of $1.00 per unit for an aggregate purchase price of $5,549,999. In addition, we issued an aggregate of 450,000 Series A-1 Units to the Founders in exchange for their capital contributions of convertible debt totaling $450,000 owed to the Founders by Rallybio, LLC. The following table summarizes purchases of our Series A-1 Units by our directors, executive officers and holders of more than 5% of our equity and their respective affiliates.

NAME OF UNITHOLDER	ACQUISITION DATE	NUMBER OF SERIES A-1 CONVERTIBLE PREFERRED UNITS	AGGREGATE PURCHASE PRICE
5AM Ventures V, L.P. (1)	April 20, 2018	1,795,946	$ 1,795,946
Canaan XI L.P. (2)	April 20, 2018	1,795,946	$ 1,795,946
New Leaf Ventures III, L.P. (3)	April 20, 2018	1,795,946	$ 1,795,946
Jeffrey M. Fryer Revocable Trust dated April 18, 2011	April 20, 2018	150,000	$ 150,000
Martin W. Mackay, Ph.D.	April 20, 2018	150,000	$ 150,000
Stephen Uden, MD	April 20, 2018	150,000	$ 150,000

(1) Dr. Parmar, a member of our board of directors, is a managing member of 5AM Partners V, LLC, the general partner of 5AM Ventures V, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by 5AM Ventures V, L.P. 5AM Ventures V, L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(2) Dr. Shannon, a member of our board of directors, is a manager of Canaan Partners XI LLC, the general partner of Canaan XI L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by Canaan XI L.P. Canaan XI L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(3) Mr. Hunt, a member of our board of directors, is a managing director at New Leaf Venture Partners, L.L.C., an entity affiliated with New Leaf Ventures III, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by New Leaf Ventures III, L.P. New Leaf Ventures III, L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

Series A-2 Preferred Units

In April 2019, we completed the sale of 7,826,083 shares of our Series A-2 Units to investors and 521,740 Series A-2 Units to the Founders and employees at a purchase price of $1.15 per unit for an aggregate purchase price of $9,599,996. In July 2019, we completed the sale of 8,695,652 shares of our Series A-2 Units to investors at a purchase price of $1.15 per unit for an aggregate purchase price of $10,000,000. In October 2019, we completed the sale of 10,434,781 shares of our Series A-2 Units to investors at a purchase price of $1.15 per unit for an aggregate purchase price of $11,999,998. The following table summarizes purchases of our Series A-2 Units by our directors, executive officers and holders of more than 5% of our equity and their respective affiliates.

NAME OF UNITHOLDER	ACQUISITION DATE	NUMBER OF SERIES A-2 CONVERTIBLE PREFERRED UNITS	AGGREGATE PURCHASE PRICE
5AM Ventures V, L.P. (1)	April 5, 2019	2,538,190	$ 2,918,919
Canaan XI L.P. (2)	April 5, 2019	2,538,190	$ 2,918,919
New Leaf Ventures III, L.P. (3)	April 5, 2019	2,538,190	$ 2,918,919
Mainstar Trst, Cust. FBO Jeffrey M. Fryer R2180643	April 5, 2019	100,000	$ 115,000
Martin W. Mackay, Ph.D.	April 5, 2019	100,000	$ 115,000
Stephen Uden, M.D.	April 5, 2019	100,000	$ 115,000
Steven Ryder, M.D.	April 5, 2019	100,000	$ 115,000
5AM Ventures V, L.P. (1)	July 23, 2019	2,820,211	$ 3,243,243
Canaan XI L.P. (2)	July 23, 2019	2,820,211	$ 3,243,243
New Leaf Ventures III, L.P. (3)	July 23, 2019	2,820,211	$ 3,243,243
5AM Ventures V, L.P. (1)	October 8, 2019	3,384,253	$ 3,891,891
Canaan XI L.P. (2)	October 8, 2019	3,384,253	$ 3,891,891
New Leaf Ventures III, L.P. (3)	October 8, 2019	3,384,253	$ 3,891,891

(1) Dr. Parmar, a member of our board of directors, is a managing member of 5AM Partners V, LLC, the general partner of 5AM Ventures V, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by 5AM Ventures V, L.P. 5AM Ventures V, L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(2) Dr. Shannon, a member of our board of directors, is a manager of Canaan Partners XI, LLC, the general partner of Canaan XI L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by Canaan XI L.P. Canaan XI L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(3) Mr. Hunt, a member of our board of directors, is a managing director at New Leaf Venture Partners, L.L.C., an entity affiliated with New Leaf Ventures III, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by New Leaf Ventures III, L.P. New Leaf Ventures III, L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

Series B Preferred Units

In March 2020, or the Initial Closing, we entered into a Series B Preferred Share Purchase Agreement, or the Series B Agreement, to initially sell up to 92,269,898 Series B Preferred Units, or the Series B Units, at a purchase price of $1.4824 per unit. At the Initial Closing, we completed the sale of 61,457,763 shares of Series B Units to investors at a purchase price of $1.4824 per unit for an aggregate purchase price of $91,104,988. In addition, the Series B Agreement gave us an option to sell up to an additional 27,606,455 Series B Units within 60 days of the Initial Closing. In April 2020, or the Second Closing, we completed the sale of 1,416,621 shares of Series B Units to investors at a purchase price of $1.4824 per unit for an aggregate purchase price of $2,099,999.

In May 2020, or the Final Closing, we completed the sale of 37,402,537 shares of Series B Units to investors at a purchase price of $1.3903 per unit, or the Updated Purchase Price, for an aggregate purchase price of $51,999,999. To ensure the investors who participated in the Initial Closing and the Second Closing, or the Initial Purchasers, received the benefit of the Updated Purchase Price, the LLC Entity issued additional Series B Units, for no additional consideration, to the Initial Purchasers such that the number of Series B Units that each Initial Purchaser held as of the Final Closing was increased to the number of Series B Units that each Initial Purchaser

would have received with the Updated Purchase Price in respect of the aggregate purchase price paid by each investor. The LLC Entity issued an aggregate of 4,072,180 additional Series B Units to the investors who participated in the Initial Closing, and an aggregate of 93,864 additional Series B Units to the investors who participated in the Second Closing. The following table summarizes purchases of units of our Series B Units by our directors, executive officers and holders of more than 5% of our equity and their respective affiliates.

NAME OF UNITHOLDER	ACQUISITION DATE(S) (1)	NUMBER OF SERIES B CONVERTIBLE PREFERRED UNITS (2)	AGGREGATE PURCHASE PRICE
Viking Global Opportunities Illiquid Investments Sub-Master LP	May 14, 2020	21,578,387	$ 30,000,000
The Rise Fund Rascal L.P. (3)	May 14, 2020	14,385,591	$ 19,999,999
Entities affiliated with 5AM Ventures (4)	March 27, 2020	12,227,750	$ 16,999,996
Pivotal bioVenture Partners Fund I L.P. (5)	March 27, 2020	10,789,193	$ 14,999,999
F-Prime Capital Partners Life Sciences Fund VI LP	March 27, 2020	10,789,193	$ 14,999,999
Entities affiliated with Tekla Capital Management LLC	March 27, 2020	10,789,190	$ 14,999,998
Canaan XI L.P. (6)	March 27, 2020	4,315,676	$ 5,999,998
New Leaf Ventures III, L.P. (7)	March 27, 2020	2,157,838	$ 2,999,999
Mainstar Trst, Cust. FBO Jeffrey M. Fryer R2180643	March 27, 2020	107,891	$ 149,999
Martin W. Mackay, Ph.D.	March 27, 2020	107,891	$ 149,999
Stephen Uden, M.D.	March 27, 2020	107,891	$ 149,999
Steven Ryder, M.D.	March 27, 2020	143,855	$ 199,999

(1) Represents the date in which the unitholder first acquired Series B Units.

(2) Reflects aggregate ownership of Series B Units, including all Series B Units acquired at the Final Closing, if applicable.

(3) Dr. Iancovici, a member of our board of directors, is a Managing Director of TPG Growth, an affiliated entity of The Rise Fund Rascal L.P. Dr. Iancovici has no voting or investment power with respect to the shares held by The Rise Fund Rascal L.P. The Rise Fund Rascal L.P. holds more than 5% of our voting stock prior to this offering.

(4) Dr. Parmar, a member of our board of directors, is a managing member of 5AM Partners V, LLC, the general partner of 5AM Ventures V, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by 5AM Ventures V, L.P. Dr. Parmar is also a managing partner of 5AM Opportunities I (GP), LLC, the general partner of 5AM Opportunities I, L.P. Entities affiliated with 5AM Ventures, including 5AM Ventures V, L.P. and 5AM Opportunities I, L.P., collectively hold more than 5% of our voting stock prior to this offering.

(5) Dr. Hopfner, a member of our board of directors, is a managing partner at Pivotal bioVenture Partners, an affiliated entity of Pivotal bioVenture Partners Fund I L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by Pivotal bioVenture Partners I L.P. Pivotal bioVenture Partners I L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(6) Dr. Shannon, a member of our board of directors, is a manager of Canaan Partners XI LLC, the general partner of Canaan XI L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by Canaan XI L.P. Canaan XI L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

(7) Mr. Hunt, a member of our board of directors, is a managing director at New Leaf Venture Partners, L.L.C., an entity affiliated with New Leaf Ventures III, L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by New Leaf Ventures III, L.P. New Leaf Ventures III, L.P. and its affiliates hold more than 5% of our voting stock prior to this offering.

Director Affiliations

Some of our directors are affiliated with and, prior to the closing of this offering have served on our board of directors as representatives of entities which beneficially own or owned 5% or more of our voting securities, as indicated in the table below:

DIRECTOR	AFFILIATED EQUITYHOLDER
Kush Parmar, M.D., Ph.D.	5AM Ventures V, L.P. and 5AM Opportunities I, L.P.
Timothy M. Shannon, M.D.	Canaan XI L.P.
Lucian Iancovici, M.D.	The Rise Fund Rascal L.P.
Ronald Hunt	New Leaf Ventures III, L.P.
Rob Hopfner, R.Ph., Ph.D.	Pivotal bioVenture Partners Fund I L.P.

Operating Agreement

Pursuant to the terms of our Operating Agreement, we have granted certain unitholders certain information rights and the right to participate in future stock issuances, which rights terminate prior to the consummation of this offering, as well as certain registration rights. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

Pursuant to the terms of our Operating Agreement, the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, who continue to so serve: Mses. Helen M. Boudreau and Paula Soteropoulos, Drs. Rob Hopfner, Lucian Iancovici, Martin W. Mackay, Kush Parmar, Timothy M. Shannon, and Mr. Ronald Hunt.

The Operating Agreement will terminate prior to the consummation of this offering, and members previously elected to our board of managers pursuant to such agreement will serve as directors of the Corporation until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Composition of the Board of Directors.”

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors’ and officers’ liability insurance. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Related Person Transaction Policy

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act of 1933, as amended, or the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years, in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked with considering all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock at , 2021, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person who we know beneficially owns more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

Percentage ownership of our common stock before this offering is based on shares of our common stock outstanding as of , 2021, after giving effect to the Reorganization, including the issuance by the Corporation of an aggregate of shares of its common stock and the subsequent distribution of those shares to members of the LLC Entity in the Liquidation, prior to the completion of this offering, as if such distribution had occurred as of , 2021, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. Percentage ownership of our common stock after this offering is based on shares of our common stock outstanding as of , 2021, after giving effect to the transactions as described above and our issuance of shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of , 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 234 Church Street, Suite 1020, New Haven CT, 06510.

NAME OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
5% or greater stockholders:			
Entities affiliated with 5AM Ventures (1)		%	%
Viking Global Opportunities Illiquid Investments Sub-Master LP (2)		%	%
Canaan XI L.P. (3)		%	%
The Rise Fund Rascal, L.P. (4)		%	%
New Leaf Ventures III, L.P. (5)		%	%
F-Prime Capital Partners Life Sciences Fund VI LP (6)		%	%
Pivotal bioVenture Partners Fund I L.P. (7)		%	%
Tekla Capital Management LLC (8)		%	%
Directors and Named Executive Officers:			
Martin W. Mackay, Ph.D.		%	%
Helen M. Boudreau		%	%
Rob Hopfner, R.Ph., Ph.D.		%	%
Ronald M. Hunt		%	%
Lucian Iancovici, M.D.		%	%
Kush M. Parmar, M.D., Ph.D.		%	%
Timothy M. Shannon, M.D.		%	%
Paula Soteropoulos		%	%
Jeffrey M. Fryer, CPA		%	%
Stephen Uden, M.D.		%	%
Steven Ryder, M.D.		%	%
All executive officers and directors as a group (11 persons)		%	%

* Less than 1%

(1) Consists of (i) shares of common stock to be received in the Reorganization in respect of shares of Series A-1 preferred units held by 5AM Ventures V, L.P.; (ii) shares of common stock to be received in the Reorganization in respect of shares of Series A-2 preferred units held by 5AM Ventures V, L.P.; (iii) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by 5AM Ventures V, L.P and (iv) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by 5AM Opportunities I, L.P. 5AM Partners V, LLC is the general partner of 5AM Ventures V, L.P. and may be deemed to have sole investment and voting power over the shares held by 5AM Ventures V, L.P. Dr. Kush Parmar is a managing member of 5AM Partners V, LLC, and may be deemed to share voting and dispositive power over the shares held by 5AM Ventures V, L.P. 5AM Opportunities I (GP), LLC is the general partner of 5AM Opportunities I, L.P. and may be deemed to have sole investment and voting power over the shares held by 5AM Opportunities I, L.P. Dr. Parmar is a managing member of 5AM Opportunities I (GP), LLC, and may be deemed to share voting and dispositive power over the shares held by 5AM Opportunities I, L.P. Dr. Parmar is also a member of our board of directors. The address of the above persons and entities is 501 2nd Street, Suite 350, San Francisco, California 94107.

(2) Consists of shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Viking Global Opportunities Illiquid Investments Sub-Master LP, or the Opportunities Fund. The Opportunities Fund has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC, or the Opportunities GP, and by Viking Global Investors LP, which provides managerial services to the Opportunities Fund. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI) and Opportunities GP, have shared authority to direct the voting and disposition of investments beneficially owned by VGI and Opportunities GP. The address of the above entities is c/o Viking Global Opportunities Illiquid Investments Sub-Master LP, 280 Park Avenue, New York, New York 10017.

(3) Consists of (i) shares of common stock to be received in the Reorganization in respect of shares of Series A-1 preferred units held by Canaan XI L.P.; (ii) shares of common stock to be received in the Reorganization in respect of shares of Series A-2 preferred units held by Canaan XI L.P.; and (iii) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Canaan XI L.P. Canaan Partners XI LLC is the general partner of Canaan XI, L.P. and may be deemed to have sole investment and voting power over the shares held by Canaan XI, L.P. Investment, voting and dispositive decisions with respect to the shares held by Canaan XI L.P. are made by the managers of Canaan XI LLC, collectively. Dr. Shannon, a

member of our board of directors, is a manager of Canaan Partners XI LLC. The address of the above person and entity is 2765 Sand Hill Road, Menlo Park, California 94025.

(4) Consists of shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by The Rise Fund Rascal, L.P., a Delaware limited partnership. The general partner of The Rise Fund Rascal, L.P. is The Rise Fund SPV GP, LLC, a Delaware limited liability company, whose managing member is The Rise Fund GenPar, L.P., a Delaware limited partnership, whose general partner is The Rise Fund GenPar Advisors, LLC, a Delaware limited liability company, whose sole member is TPG Holdings I, L.P., a Delaware limited partnership, whose general partner is TPG Holdings IA, LLC, a Delaware limited liability company, whose sole member is TPG Group Holdings (SBS), L.P., a Delaware limited partnership, whose general partner is TPG Group Holdings (SBS) Advisors, LLC, a Delaware limited liability company, whose sole member is TPG Group Holdings (SBS) Advisors, Inc., a Delaware corporation. David Bonderman and James G. Coulter are the sole shareholders of TPG Group Holdings (SBS) Advisors, Inc. and may therefore be deemed to beneficially own the securities held by The Rise Fund Rascal, L.P. Messrs. Bonderman and Coulter disclaim beneficial ownership of the securities held by The Rise Fund Rascal, L.P. except to the extent of their pecuniary interest therein. Dr. Lucian Iancovici, a member of our board of directors, is a Managing Director of TPG Growth, an affiliated entity of The Rise Fund Rascal, L.P. Dr. Iancovici has no voting or dispositive power over the shares held by The Rise Fund Rascal, L.P. The address of each of The Rise Fund Rascal, L.P., Messrs. Bonderman and Coulter and Dr. Iancovici is 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102.

(5) Consists of (i) shares of common stock to be received in the Reorganization in respect of shares of Series A-1 preferred units held by New Leaf Ventures III, L.P.; (ii) shares of common stock to be received in the Reorganization in respect of shares of Series A-2 preferred units held by New Leaf Associates III, L.P.; and (iii) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by New Leaf Ventures III, L.P. New Leaf Venture Management III, L.L.C. is the general partner of New Leaf Associates III, L.P., which in turn is the General Partner of New Leaf Ventures III, L.P., and may be deemed to have sole investment and voting power over the shares held by New Leaf Ventures III, L.P. Ronald Hunt is a managing director at New Leaf Venture Partners, L.L.C. and may be deemed to share voting and dispositive power over the shares held by New Leaf Ventures III, L.P. Mr. Hunt is also a member of our board of directors. The address of the above person and entity is 420 Lexington Avenue, Suite 408, New York, New York 10170.

(6) Consists of shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by F-Prime Capital Partners Life Sciences Fund VI LP. F-Prime Capital Partners Life Sciences Advisors Fund VI LP, or F-Prime Advisors, is the general partner of F-Prime Capital Partners Life Sciences Fund VI LP. F-Prime Advisors is solely managed by Impresa Management LLC, the managing member of its general partner and its investment manager. Impresa Management LLC is owned, directly or indirectly, by various shareholders and employees of FMR LLC. Each of the entities listed above expressly disclaims beneficial ownership of the securities listed above except of any pecuniary interest therein, if any. The address of the above entities is 245 Summer Street, Boston, Massachusetts 02210.

(7) Consists of shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Pivotal bioVenture Partners Fund I, L.P. Pivotal bioVenture Partners Fund I G.P., L.P. is the general partner of Pivotal bioVenture Partners Fund I, L.P. and may be deemed to have sole investment and voting power over the shares held by Pivotal bioVenture Partners Fund I, L.P. Dr. Rob Hopfner is a managing partner at Pivotal bioVenture Partners and may be deemed to share voting and dispositive power over the shares held by Pivotal bioVenture Partners Fund I, L.P. Dr. Hopfner is also a member of our board of directors. The principal business address of Pivotal bioVenture Partners Fund I, L.P. is 501 Second Street, Suite 200, San Francisco, CA 94107.

(8) Consists of (i) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Tekla Healthcare Investors, (ii) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Tekla Healthcare Opportunities Fund and (iii) shares of common stock to be received in the Reorganization in respect of shares of Series B preferred units held by Tekla Life Sciences Investors. Tekla Capital Management LLC, or TCM, is an investment adviser to Tekla Healthcare Investors (NYSE: HQH), Tekla Healthcare Opportunities Fund (NYSE: THQ) and Tekla Life Sciences Investors (NYSE: HQL), collectively referred to as the Tekla Funds. Daniel R. Omstead, Ph.D., serves as President and Chief Executive Officer of the Tekla Funds. Each of TCM and Daniel R. Omstead, through his control of TCM, has sole power to dispose of the shares beneficially owned by the Tekla Funds. Neither TCM nor Daniel R. Omstead has the sole power to vote or direct the vote of the shares beneficially owned by the Tekla Funds, which power resides in the Board of Trustees for each Tekla Fund. TCM carries the voting of shares under written guidelines established by the Board of Trustees. The address for the Tekla Funds is 100 Federal Street, 19th Floor, Boston, Massachusetts 02110.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws as they will be in effect prior to the consummation of this offering are summaries and are qualified in their entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect prior to the consummation of this offering. Copies of these documents are filed as exhibits to the registration statement of which this prospectus is a part. The description of our common stock reflects the completion of the Reorganization, which will occur immediately prior to the completion of this offering. See "The Reorganization" for more information concerning the Reorganization.

General

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, with a par value of $ per share, and shares of preferred stock, with a par value of $ per share, all of which preferred stock will be undesignated.

As of March 31, 2021, assuming the Reorganization and the closing of this offering, there were shares of common stock outstanding, held by stockholders of record, and no shares of preferred stock outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive an amount of our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation that will be in effect prior to the consummation of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Investor Rights Agreement

The LLC Entity is party to an Amended and Restated Investor Rights Agreement with the investors party to our Operating Agreement, or the Investor Rights Agreement. Pursuant to the terms of this agreement, we granted these stockholders certain information rights and the right to participate in future stock issuances, which rights terminate prior to the consummation of this offering, as well as certain registration rights. Following the Reorganization, we will enter into a registration rights agreement, described below, with the shareholders of Rallybio Corporation, or the Corporation, immediately prior to the completion of this offering.

Registration Rights

Following the Reorganization and prior to the completion of this offering, we will enter into a Registration Rights Agreement with the shareholders of the Corporation, or the Registration Rights Agreement. The Registration Rights Agreement will grant the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (i) the shares of our common stock held by our shareholders following the Reorganization and prior to the consummation of this offering and (ii) any common stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clause (i) above. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Registration Rights Agreement, we will pay all expenses relating to such registrations, including the fees of one counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Registration Rights Agreement will also include customary indemnification and procedural terms.

Holders of shares of our common stock (after giving effect to the Reorganization, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the subsequent conversion of preferred stock into shares of our common stock) will be entitled to such registration rights pursuant to the Registration Rights Agreement. These registration rights will expire on the earlier of (i) such time after this offering as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration and (ii) the third anniversary of the consummation of this offering.

Demand Registration Rights

At any time beginning 180 days after the effectiveness of the registration statement of which this prospectus forms a part, the holders of at least 30% of the registrable securities then outstanding may request that we file a registration statement on Form S-1 with respect to at least 20% of the registrable securities then outstanding, if the aggregate offering price of the registrable securities requested to be registered would exceed $20 million.

Once we are eligible to use a registration statement on Form S-3, the holders of not less than 25% of the registrable shares then outstanding may request that we file a registration statement on Form S-3 with respect to such holders' registrable securities then outstanding, if the aggregate offering price of the registrable securities requested to be registered would exceed $3 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Investor Rights Agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

Anti-takeover Effects of Our Amended and Restated Certificate of Incorporation and Our Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws, which will be in effect prior to the consummation of this offering, will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors, but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified board. Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have

the effect of making it more difficult for stockholders to change the composition of our board of directors. Our amended and restated certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have members.

Action by written consent; special meetings of stockholders. Our amended and restated certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our amended and restated certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of directors. Our amended and restated certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board of directors.

Advance notice procedures. Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority approval requirements. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our amended and restated certificate of incorporation and bylaws will provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors will be required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our amended and restated certificate of incorporation and bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our amended and restated certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or to any claim for which the federal courts have

exclusive jurisdiction. Our amended and restated certificate of incorporation will also provide that, unless we consent in writing to the selection of an alternative forum, the U.S. federal district courts shall be the exclusive forum for the resolution of any claims arising under the Securities Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware and certain federal securities law, these provisions may have the effect of discouraging lawsuits against our directors and officers. See "Risk Factors—Risks Related to This Offering and Our Common Stock—Our amended and restated certificate of incorporation will designate the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees."

Section 203 of the DGCL

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the corporation's board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is .

Listing

We intend to apply to have our common stock approved for listing on the Nasdaq Global Market under the symbol " ".

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See “Risk Factors—Risks Related to This Offering and Our Common Stock—A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.” Furthermore, although we intend to apply to have our common stock approved for listing on the Nasdaq Global Market, we cannot assure you that there will be an active public trading market for our common stock.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of , 2021, and after giving effect to the Reorganization, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the subsequent conversion of preferred stock into shares of our common stock, we will have an aggregate of shares of our common stock outstanding (or shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock, all of the shares sold in this offering (or shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be “restricted securities” as such term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, who will collectively own shares of our common stock upon the closing of this offering (based on our shares outstanding as of , 2021, and after giving effect to the Reorganization, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the subsequent conversion of preferred stock into shares of our common stock, have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Jefferies LLC and Cowen and Company, LLC.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see “Underwriting.”

After the date of the initial public filing of the prospectus, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Securities Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has

beneficially owned shares of our common stock for at least six months would be entitled to sell (subject to the lock-up agreement referred to above, if applicable) in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the total number of shares then outstanding of our common stock, which will equal approximately shares (or shares if the underwriters exercise their option to purchase additional shares in full) of our common stock immediately after this offering; or
- the average weekly trading volume in shares of our common stock on the during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us (as well as the lock-up agreement referred to above, if applicable). If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our incentive plans. We expect to file the registration statement covering shares offered pursuant to our incentive plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Registration rights

Upon the closing of this offering, the holders of shares of our common stock or their transferees (after giving effect to the Reorganization, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the subsequent conversion of preferred stock into shares of our common stock) will be entitled to various rights with respect to the registration of these

shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case, in effect as of the date hereof.

These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships or other pass-through entities for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- persons who hold common stock that constitutes "qualified small business stock" under Section 1202 of the Code, or "Section 1244 stock" under Section 1244 of the Code;
- persons who acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that acquired our common stock pursuant to the exercise of warrants or conversion rights under convertible instruments;
- persons who have elected to mark securities to market;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

This discussion does not address the tax treatment of entities or arrangements treated as partnerships or other pass-through entities or arrangements, or persons who hold our common stock through partnerships or other

pass-through entities or arrangements, for U.S. federal income tax purposes. If an entity or arrangement treated as a partnership or other pass-through entity for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner, member, or other beneficial owner of such partnership or other pass-through entity will depend on the status of such partner, member, or other beneficial owner, the activities of the partnership or other pass-through entity, and certain determinations made at the level of the partner, member, or other beneficial owner, as applicable. Accordingly, partnerships or other pass-through entities holding our common stock and the partners, members and other beneficial owners thereof should consult their tax advisors regarding the U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or any other entity taxable as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying any distributions to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, FATCA, and backup withholding, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal tax withholding at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate. This certification must be provided to us or the applicable withholding agent before the payment of dividends and must be updated periodically. If the Non-U.S. Holder holds our common stock through a financial institution or other agent acting on the Non-U.S. Holder’s behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment of fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below on backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes, at any time during the five-year period preceding such disposition (or the Non-U.S. Holder's holding period, if shorter).

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such gain, as adjusted for certain items.

A non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. Generally, a corporation is a USRPHC if the fair market value of its USRPIs equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we are not currently a USRPHC or will not become a USRPHC in the future.

Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" (as defined by applicable Treasury Regulations) on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the Non U.S. Holder either certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI or otherwise establishes an exemption. We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions, regardless of whether any distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the Non U.S. Holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting. Non-U.S. Holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections together with any related Treasury Regulations, other Treasury Department and IRS guidance issued thereunder, and intergovernmental agreements, legislation, rules and other official guidance adopted pursuant to such intergovernmental agreements, commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless such institution furnishes proper documentation (typically on IRS Form W-8BEN-E) indicating that (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have also applied to payments of gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers and withholding agents generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

If withholding under FATCA is required on any payment related to our common stock, investors not otherwise subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) on such payment may be entitled to seek a refund or credit from the IRS. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2021, among us and Jefferies LLC, Cowen & Company, LLC and Evercore Group L.L.C., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Cowen & Company, LLC	
Evercore Group L.L.C.	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. After the offering, the initial public offering price and concession to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to pay the filing fees incident to, and the fees and disbursements of counsel for the underwriters in connection with, the clearance of this offering by the Financial Industry Regulatory Authority, Inc. in an amount up to $.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We intend to apply for listing of our common stock on the Nasdaq Global Market under the symbol " ".

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all, or substantially all, our outstanding capital stock, have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act,

- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Cowen & Company, LLC.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC and Cowen & Company, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail, or on the web sites or through online services, maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in EEA

In relation to each member state of the European Economic Area which has implemented the Prospectus Regulation, or each, a Relevant Member State, no offer of shares of our common stock which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State, except that with effect from and including the Relevant Implementation Date, an offer of such shares of our common stock may be made to the public in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives of the underwriters; or
- in any other circumstances falling within Article 3(2) of the Prospectus Regulation,

provided that no such offer of shares of our common stock shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 16 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of our common stock to be offered so as to enable an investor to

decide to purchase or subscribe the shares of our common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Regulation in that Relevant Member State, and the expression "Prospectus Regulation" means Prospectus Regulation (EU) 2017/1129 (and amendments thereto, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State.

Notice to Prospective Investors in United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to our shares of common stock which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Section 86 of the FSMA, provided that no such offer of the shares shall require the Company or the underwriters to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Notice to Prospective Investors in Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia, you confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with us under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares of our common stock issued to you pursuant to this prospectus for resale in Australia within 12 months of those shares of our common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Hong Kong

No shares of our common stock have been offered or sold, and no shares of our common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and

Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32) or the Securities and Futures Ordinance (Cap. 571) of Hong Kong. No document, invitation or advertisement relating to the shares of our common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the shares of our common stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of our common stock will be required, and is deemed by the acquisition of the shares of our common stock, to confirm that he is aware of the restriction on offers of the shares of our common stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of our common stock in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of our common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any shares of our common stock, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from S-30 the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase, of the shares of our common stock may not be issued, circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Switzerland

The shares of our common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus, nor any other offering or marketing material, relating to the shares of our common stock, or the offering, may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus, nor any other offering or marketing material relating to the offering, us or the shares of our common stock, have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with and the offer of shares of our common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares of our common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares of our common stock.

Notice to Prospective Investors in Canada

(A) Resale Restrictions

The distribution of shares of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these shares of our common stock are made. Any resale of the shares of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of our common stock.

(B) Representations of Canadian Purchasers

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of our common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—Prospectus Exemptions,

- the purchaser is a “permitted client” as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that each of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well, as the experts named herein, may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of shares of our common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of our common stock in their particular circumstances and about the eligibility of the shares of our common stock for investment by the purchaser under relevant Canadian legislation.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ropes & Gray, LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York.

EXPERTS

The financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto.

Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be accessed at the SEC's website referenced above. We also intend to make this information available on the investor relations section of our website, which is located at www.rallybio.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the members and the Board of Managers of Rallybio Holdings, LLC

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rallybio Holdings, LLC and subsidiaries (the “Company”) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred units and members’ deficit, and cash flows, for each of the years then ended and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Hartford, Connecticut
April 27, 2021

We have served as the Company’s auditor since 2018.

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except share and per share amounts)	AS OF DECEMBER 31, 2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 140,233	$ 19,458
Prepaid expenses and other assets	1,028	1,462
Total current assets	141,261	20,920
Property and equipment, net	287	199
Investment in joint venture	310	488
Total assets	$ 141,858	$ 21,607
Liabilities and members' deficit		
Current liabilities:		
Accounts payable	$ 1,579	$ 857
Accrued expenses	4,264	2,949
Total current liabilities	5,843	3,806
Accrued expenses long-term	12	941
Total liabilities	5,855	4,747
Commitments and contingencies (Note 10)		
Redeemable convertible preferred units:		
Series A preferred units, no par value, 33,478,255 units authorized, issued and outstanding as of December 31, 2020 and 2019; liquidation preference of $37,600 as of December 31, 2020 and 2019	37,141	37,141
Series B preferred units, no par value, 104,442,965 units authorized, issued and outstanding as of December 31, 2020; liquidation preference of $145,204 as of December 31, 2020	144,886	—
Members' deficit:		
Common units, no par value, 5,700,000 authorized, issued and outstanding as of December 31, 2020 and 2019	452	230
Incentive units, 17,772,360 and 6,033,957 authorized, 6,865,704 and 1,633,000 issued and outstanding as of December 31, 2020 and 2019, respectively	538	56
Accumulated deficit	(47,014)	(20,567)
Total members' deficit	(46,024)	(20,281)
Total liabilities, redeemable convertible preferred units, and members' deficit	$ 141,858	$ 21,607

See accompanying notes of the consolidated financial statements

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)	YEAR ENDED DECEMBER 31, 2020	2019
Operating Expenses:		
Research and development	$ 17,630	$ 11,366
General and administrative	7,673	6,276
Total operating expenses	25,303	17,642
Loss from operations	(25,303)	(17,642)
Other income (expenses):		
Interest income	171	197
Interest expense	(49)	(39)
Other income and expense	241	167
Change in fair value of Series A-2 financing right obligation	—	(143)
Total other income, net	363	182
Loss before income taxes	(24,940)	(17,460)
Income tax benefit	(15)	—
Loss on investment in joint venture	1,522	103
Net loss and comprehensive loss	$ (26,447)	$ (17,563)
Net loss attributable to common units	$ (26,447)	$ (17,563)
Net loss per common unit, basic and diluted	$ (9.95)	$ (10.24)
Weighted average common units outstanding, basic and diluted	2,659,187	1,715,164

See accompanying notes of the consolidated financial statements

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES

Consolidated Statements of Changes in Redeemable Convertible Preferred Units and Members' Deficit

(in thousands, except share amounts)	SERIES A REDEEMABLE CONVERTIBLE PREFERRED UNITS		SERIES B REDEEMABLE CONVERTIBLE PREFERRED UNITS		COMMON UNITS		INCENTIVE UNITS		ACCUMULATED	TOTAL MEMBERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	DEFICIT	
Balance, December 31, 2018	5,999,999	$ 3,066	—	$ —	5,700,000	$ 90	210,000	$ 2	$ (3,004)	$ (2,912)
Issuance of Series A-2 Redeemable Convertible Preferred Units, net of issuance costs of $33	27,478,256	34,075	—	—	—	—	—	—	—	—
Incentive unit-based compensation	—	—	—	—	—	—	1,423,000	54	—	54
Common unit-based compensation	—	—	—	—	—	140	—	—	—	140
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(17,563)	(17,563)
Balance, December 31, 2019	33,478,255	$ 37,141	—	$ —	5,700,000	$ 230	1,633,000	$ 56	$ (20,567)	$ (20,281)
Issuance of Series B Redeemable Convertible Preferred Units, net of issuance costs of $319	—	—	104,442,965	144,886	—	—	—	—	—	—
Incentive unit-based compensation	—	—	—	—	—	—	5,232,704	482	—	482
Common unit-based compensation	—	—	—	—	—	222	—	—	—	222
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(26,447)	(26,447)
Balance, December 31, 2020	33,478,255	$ 37,141	104,442,965	$144,886	5,700,000	$ 452	6,865,704	$ 538	$ (47,014)	$ (46,024)

See accompanying notes of the consolidated financial statements

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(in thousands, except share amounts)	YEAR ENDED DECEMBER 31, 2020	2019
Cash Flows from Operating Activities		
Net loss	$ (26,447)	$ (17,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	62	26
Equity based compensation	704	194
Change in fair value of Series A-2 financing right obligation	—	143
Other	—	1
Loss on investment in joint venture	1,522	103
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	434	(1,381)
Accounts payable	723	728
Accrued expenses	963	2,723
Net cash used in operating activities	(22,039)	(15,026)
Cash Flows used in Investing Activities:		
Purchase of property and equipment	(137)	(188)
Investment in joint venture	(1,935)	—
Net cash used in investing activities	(2,072)	(188)
Cash Flows from Financing Activities:		
Issuance of Series A preferred units	—	31,600
Issuance of Series B preferred units	145,205	—
Preferred unit issuance costs	(319)	(33)
Net cash provided by financing activities	144,886	31,567
Net increase in cash and cash equivalents	120,775	16,353
Cash and cash equivalents—beginning of year	19,458	3,105
Cash and cash equivalents—end of year	$ 140,233	$ 19,458
Supplemental Schedule of Noncash Investing and Financing Activities:		
(Decrease) in Series A-2 financing right obligation	$ —	$ (2,509)
Unfunded investment in joint venture	$ —	$ 590
Accrued expenses for purchases of property and equipment	$ 14	$ —

See accompanying notes of the consolidated financial statements

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements

1. BUSINESS

Rallybio Holdings, LLC holds 100% of the outstanding membership units in five wholly-owned subsidiaries—Rallybio, LLC, Rallybio IPA, LLC, Rallybio IPB, LLC, Rallybio, IPD, LLC, and IPC Research, LLC (collectively, the "Company"). Rallybio Holdings, LLC was incorporated in Delaware on March 22, 2018. The Company is a clinical-stage biotechnology company built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing, and delivering therapies to meaningfully improve the lives of patients suffering from severe and rare diseases.

The Company has raised $37.6 million in Series A-1 and A-2 financing and $145.2 million in Series B financing. Refer to Note 6 "Redeemable Convertible Preferred Units".

The Company is seeking to complete an initial public offering ("IPO"). Prior to the completion of the IPO, the Company intends to complete a series of transactions pursuant to which (i) Rallybio IPD, LLC, will be converted from a Delaware limited liability company to a Delaware corporation (the "Corporation"), (ii) the Corporation will form four direct subsidiaries (collectively the "Merger Subs"), (iii) each of Rallybio Holdings, LLC's other four direct subsidiaries (collectively the "Asset Subsidiaries") will consummate a separate merger each with one of the Merger Subs, with the Asset Subsidiaries surviving the mergers and Rallybio Holdings, LLC receiving common stock of the Corporation in exchange for its interest in each Asset Subsidiary, which will result in the Asset Subsidiaries becoming subsidiaries of the Corporation and the Corporation becoming the only direct subsidiary of Rallybio Holdings, LLC, and (iv) following this series of mergers, Rallybio Holdings, LLC will liquidate and distribute 100% of the stock of the Corporation to the common and preferred unitholders of Rallybio Holdings, LLC. These transactions are collectively referred to as the "Reorganization." As a result of the Reorganization, the unitholders of Rallybio Holdings, LLC will become the stockholders of the Corporation, and the Corporation will become successor to Rallybio Holdings, LLC and the issuer of common stock in the IPO, and the Company's consolidated financial statements will be reported from the Corporation.

On March 2020, the World Health Organization characterized the novel coronavirus as a global pandemic. Although there is significant uncertainty as to the likely effects this disease may have in the future, to date there has not yet been a significant impact to the Company's operations or financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES BASIS OF PRESENTATION AND PRINCIPLES OF CONSOLIDATION

Basis of Presentation—The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted ("GAAP") in the United States. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

Principles of Consolidation—The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates—The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements. While management believes that estimates and assumptions used in the preparation of the consolidated financial statements are appropriate, actual results could differ from those estimates. The most significant estimates are those used in the determination of the fair value of its common units and incentive units awarded to employees, for purposes of recording equity-based incentive compensation, as well as contracted research and development accruals.

Liquidity and Ability to Continue as a Going Concern—The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Management has evaluated whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going

concern within one year after the date the financial statements are issued. Since its inception, the Company has incurred net losses and negative cash flows from operations.

During the years ended December 31, 2020 and December 31, 2019, the Company incurred a net loss of $26.4 million and $17.6 million, respectively, and used $22.0 million and $15.0 million in cash for operations, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of $47.0 million. The Company expects to continue to generate operating losses and negative cash flows in the foreseeable future.

The Company currently expects that the cash and cash equivalents on hand of $140.2 million as of December 31, 2020, will be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date the consolidated financial statements are issued. Additional funding will be needed to finance future clinical, pre-clinical, manufacturing, and commercial activities. To date, the Company has principally financed its operations through private placements of redeemable convertible preferred units. In the event the Company does not complete an IPO, the Company will seek additional funding through private equity and debt financings and other arrangements. There is no assurance the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and it may not be able to enter into other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate our research and development programs, portfolio expansion or commercialization efforts, which could adversely affect its business prospects and ability to continue operations.

The Company is subject to risks common to companies in the biopharmaceutical industry. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for its intellectual property will be maintained, that any products developed will obtain required regulatory approval, or that any approved products will be commercially viable. Even if the development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales and ultimately net income.

Variable Interest Entity—The Company evaluates its ownership, contractual, and other interests in entities to determine if it has any variable interest in a variable interest entity ("VIE"). These evaluations are complex, involve judgment, and the use of estimates and assumptions based on available historical information, among other factors. If the Company determines that an entity in which it holds a contractual, or ownership, interest is a VIE and that the Company is the primary beneficiary, the Company consolidates such entity in its consolidated financial statements. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to make decisions that most significantly affect the economic performance of the VIE; and (ii) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE. Management performs ongoing reassessments of whether changes in the facts and circumstances regarding the Company's involvement with a VIE will cause the consolidation conclusion to change. Changes in consolidation status are applied prospectively. The Company evaluated its investment in REV-I (defined in Note 9) and concluded that it represented a VIE and was not deemed the primary beneficiary. If the Company is not deemed to be the primary beneficiary in a VIE, the Company accounts for the investment or other variable interests in a VIE in accordance with the applicable GAAP (See Note 9).

Equity Method Investments—The Company accounts for investments for which it does not have a controlling interest in accordance with ASC 323, *Investments – Equity Method and Joint Ventures*. The Company recognizes its pro-rata share of income and losses in "loss on investment in joint venture" on the consolidated statements of operations and comprehensive loss, with a corresponding change to the investment in joint venture on the consolidated balance sheets.

Financial Instruments—The Company's principal financial instruments are comprised of cash and cash equivalents, accounts payable, and accrued liabilities. The carrying value of all financial instruments approximates fair value. During 2019, the Company also recorded, at fair value, a free-standing financial instrument related to the obligation to issue future Series A-2 units at pre-determined prices upon the achievement of specific milestone events. As of December 31, 2019, all Series A-2 units were sold and therefore there is no longer a financing obligation outstanding.

Concentrations of credit risk—Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. Periodically, the Company may maintain

deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits.

Cash and Cash Equivalents—The Company classifies amounts on deposit in banks and cash invested temporarily in various instruments, primarily money market accounts, with original maturities of three months or less at time of purchase as cash and cash equivalents.

Property and Equipment—Property and equipment are recorded at cost and consists of computer and other equipment, furniture and fixtures, leasehold improvements, and capitalized software. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to six years. Maintenance and repairs which do not extend the lives of the assets are charged directly to expense as incurred. Upon retirement or disposal, cost and related accumulated depreciation are removed from the related accounts, and any resulting gain or loss is recognized as a component of income or loss in the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets—When indications of potential impairments are present, the Company evaluates the carrying value of long-lived assets. The Company adjusts the carrying value of the long-lived assets if the sum of undiscounted expected future cash flows is less than carrying value. No such impairments were recorded during the years ended December 31, 2020 or 2019.

Income Taxes—Rallybio Holdings, LLC is taxed under the provisions of *Subchapter K— Partners and Partnerships* of the Internal Revenue Code. Under those provisions, Rallybio Holdings, LLC does not pay federal or state corporate income taxes on its taxable income. Instead, the members include net income or loss for Rallybio Holdings, LLC on their individual tax returns.

Rallybio, LLC, Rallybio IPA, LLC, Rallybio IPB, LLC, IPC Research, LLC, and Rallybio IPD, LLC have elected, for United States federal and state income tax purposes, to be each treated as and taxed as corporations. These entities are not eligible to file a consolidated federal income tax return and will file separately as stand-alone taxpayers. Accordingly, each entity, on a standalone basis, uses the asset and liability method of accounting for income taxes, as set forth in Accounting Standards Codification (ASC) 740, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequence of temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry forwards, all calculated using presently enacted tax rates. The Company evaluates whether deferred tax assets are more likely than not of being realized in determining whether a valuation allowance is necessary. As of December 31, 2020 and 2019, the Company determined that it is not more likely than not that deferred taxes will be realized and as a result recorded a valuation allowance against its deferred tax assets.

Research and Development Expenses—Research and development expenses are comprised of costs incurred in performing research and development activities including personnel salaries, benefits, and equity-based compensation; external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; the cost of developing and manufacturing clinical study materials, program regulatory costs, expenses associated with obligations under asset acquisitions, license agreements and other direct and indirect costs. Costs incurred in connection with research and development activities are expensed as incurred. Costs are considered incurred based on an evaluation of the progress to completion of each contract using information and data provided by the respective vendors, including the Company's clinical sites. Depending upon the timing of invoicing by the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid expenses or accrued expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Preferred Units—The Company records all preferred units at their respective fair values less issuance costs on the dates of issuance. The preferred units are recorded outside of members' deficit because, in the event of certain deemed liquidation events, which are events that are not considered solely within the Company's control, such as a merger, acquisition or sale of all or substantially all of the Company's assets, the preferred units will become

redeemable. The preferred units could also become redeemable due to certain change of control clauses that are outside of the Company's control. In the event of a change of control of the Company, proceeds received from the event will be distributed to the preferred units in accordance with the liquidation preferences set forth in the Company's Operating Agreement.

Deferred Offering Costs—The Company capitalizes certain legal, professional accounting and other third-party fees that are specific incremental costs directly attributable to an in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the common or preferred units generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. Preferred unit issuance costs are presented as a direct reduction of the carrying amount of the Series B preferred units totaled $319,265 for the year ended December 31, 2020. Preferred unit issuance costs are presented as a direct reduction of the carrying amount Series A preferred units and totaled $33,443 for the year ended December 31, 2019.

Equity-Based Compensation—The Company accounts for equity-based compensation in accordance with ASC 718, Compensation—Stock Compensation ("ASC 718"). Generally, equity-based compensation is measured at the grant date for all equity-based awards made to employees based on the fair value of the awards and is recognized over the requisite service period, which is generally the vesting period. Equity-based compensation for awards with performance conditions are recognized over the service period when achievement of the performance condition is probable. The Company has elected to recognize the actual forfeitures by reducing the equity-based compensation in the same period as the forfeitures occur. The Company classifies equity-based compensation in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified.

The Company has issued incentive units and restricted common units to employees. Incentive units granted to employees generally vest over a four-year period. The incentive units are common units issued in the form of profits interests, providing the employee with compensation equal to the increase in the value of the unit over a participation threshold of the unit, as determined at the time of grant. The incentive units have defined rights within the Company's Operating Agreement. The holder, therefore, has the right to participate in distributions of profits only in excess of such participation threshold. The participation threshold is based on the valuation of a single common unit on or around the grant date.

The fair value of the Company's restricted common units and incentive units is determined using an option pricing method ("OPM") which uses market approaches and a Black-Scholes option pricing model to estimate its enterprise value. An OPM is then used which treats common units and preferred units as call options on the total equity value of the Company, with exercise prices based on the value thresholds at which the allocation among the various holders of the Company's securities changes to value the common units of the Company. A discount for lack of marketability of the common units is then applied to arrive at an indication of value for the common units as of the valuation date. Volatility is determined by comparing companies operating in the Company's comparable industry as well as the Company's capital structure and risk profile relative to its peer group.

Fair Value Measurements—ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs for the asset or liability (i.e. supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as considers counterparty credit risk in its assessment of fair value.

The fair value of the Series A-2 financing obligation was measured on a recurring basis and is considered a Level 3 instrument in the fair value hierarchy. See Note 6 "Redeemable Convertible Preferred Units" for more information on the Series A-2 financing obligation.

The following table summarizes the Company's Series A-2 financing right obligation for the year ended December 31, 2019:

(in thousands)	
Outstanding—December 31, 2018	$ 2,366
Change in fair value of liability	143
Milestones achieved	(2,509)
Outstanding—December 31, 2019	$ —

Segment information—Operating segments are defined as components of an enterprise for which discrete financial information is regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing operating performance. The Company manages its operations as a single segment for the purposes of allocating resources, assessing performance, and making operating decisions. All tangible assets of the Company are held in the United States.

Basic and Diluted Net Loss Per Unit—The Company calculates basic net loss per unit by dividing the net loss by the weighted average number of common units outstanding during the period, without consideration of potential dilutive securities. Unvested restricted common units as of December 31, 2020 and 2019 are not considered participating securities and as such are excluded from the weighted average number of shares used for calculating basic and diluted net loss per share. Diluted net loss per unit is computed by dividing the net loss by the sum of the weighted average number of common units outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include restricted common units, incentive units, and redeemable convertible preferred units. The dilutive effect of redeemable convertible preferred units is calculated using the if-converted method. The Company has generated a net loss for all periods presented, therefore diluted net loss per unit is the same as basic net loss per unit since the inclusion of potentially dilutive securities would be anti-dilutive.

Recent Accounting Pronouncements—In February 2016, the FASB issued ASU 2016-02, *Leases*. This guidance requires an entity to recognize lease liabilities and a right-of-use asset for all leases on the balance sheet and to disclose key information about the entity's leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, with earlier adoption permitted. ASU 2016-02 must be adopted using a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

The Jumpstart Our Business Startups Act of 2012 permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. As an emerging growth company, the Company has elected to take advantage of this extended transition period.

3. ASSET ACQUISITIONS

In March 2019, the Company, through one of its wholly-owned subsidiaries, entered into an asset purchase agreement and acquired intellectual property from Swedish Orphan Biovitrum AB. The purchase price includes an upfront payment of $3.0 million with additional payments of $1.0 million due in September 2020 and March 2021. The assets were expensed upon purchase given the uncertainty of probable future revenue streams and are included in research and development expense on the consolidated statements of operations and comprehensive loss. Discounted obligations in the amount of $1.0 million and $1.9 million which includes accretion of interest, are included in accrued expenses and accrued expenses long-term on the consolidated balance sheets as of December 31, 2020 and December 31, 2019, respectively. Interest expense related to the discounted obligation was $49,422 and $39,281 for the years ended December 31, 2020 and 2019, respectively. In the event that the Company achieves certain milestones, milestone payments will become due, as well as royalties due on future sales.

In June 2019, the Company, through one of its wholly owned subsidiaries, entered into an asset purchase agreement and acquired intellectual property from Prophylix AS for $1.2 million. Pursuant to the agreement, the Company assumed liabilities for a sign on licensing fee in the amount of $0.1 million, reimbursements for a manufacturing fee in the amount of $0.5 million and manufacturing liabilities in the form of future commitments of approximately $1.2 million. The assets purchased and liabilities assumed, with the exception of the manufacturing commitment, were expensed upon purchase given the uncertainty of probable future revenue streams and are included in research and development expense on the consolidated statements of operations and comprehensive loss. Costs associated with the manufacturing commitment are expensed to research and development within the consolidated statements of operations and comprehensive loss, as the manufacturer fulfills its obligations. In the event that the Company achieves certain development and commercial milestones, milestone payments will become due, as well as royalties on future sales.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following as of December 31, 2020 and 2019:

(in thousands)	2020	2019
Computer and other equipment	$ 62	$ 43
Capitalized software	86	62
Furniture and fixtures	52	52
Leasehold improvements	184	77
Less accumulated depreciation	(97)	(35)
Property and equipment—net	$ 287	$ 199

Depreciation expense totaled $62,030 and $26,344 for the years ended December 31, 2020 and 2019, respectively.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following at December 31, 2020 and 2019:

(in thousands)	2020	2019
Employee expenses	$1,912	$1,122
Asset purchase obligation	990	1,000
Unfunded obligation in joint venture	—	590
Professional fees	185	138
Research and development	1,065	87
Other	112	12
	$4,264	$2,949

6. REDEEMABLE CONVERTIBLE PREFERRED UNITS

Preferred Units—In April 2018, Rallybio Holdings, LLC entered into a Series A Preferred Stock Purchase Agreement (the "Series A Agreement") with a total potential aggregate purchase price $37.0 million. Under the terms of the Series A Agreement, Rallybio Holdings, LLC agreed to sell 5,999,999 units of Series A-1 Redeemable Convertible Preferred Units ("Series A-1 Units") to investors at a price of $1.00 per share and up to 26,956,516 shares of Series A-2 Redeemable Convertible Preferred Units ("Series A-2 Units"), upon the Company's achievement of certain milestone events, to investors at a price of $1.15 per share (the "Series A Financing Right Obligation").

In April 2018, Rallybio Holdings, LLC sold 5,549,999 Series A-1 Units to investors in exchange for $5.5 million. Additionally, the Company issued 450,000 Series A-1 Units to the Company's founders in exchange for a capital contribution of convertible debt totaling $0.5 million owed to the founders by Rallybio, LLC.

In connection with the Series A Agreement, the Company entered into a Connecticut Presence Agreement (the "CPA") with Connecticut Innovation, Incorporated ("CII") relating to Series A-1 and Series A-2 Units that would be issued to CII. The CPA provides that the proceeds from CII's investment in the Company's preferred units be paid back to CII at a specified price. The CPA is only exercisable upon the Company's breach of the covenant which requires it to maintain a Connecticut presence, as defined within the CPA.

In connection with the Series A Agreement, the Company granted investors the right to purchase Series A-2 Units at future milestone dates and at a predetermined price. Since the investors held rights that imposed an obligation on the Company to issue Preferred Units that were potentially redeemable, the future tranche rights were considered a freestanding instrument and were recorded at the fair value of the tranche right and classified as a liability. Changes in the fair value of this liability are recorded in prior period earnings. The milestones were met during 2019, and preferred units were redeemed by the investor and the liability attributable to the tranche rights was reclassified to Series A Preferred Units, as such, the freestanding instrument and the fair value of the tranche right a liability was $0.0 as of December 31, 2019. Refer to Note 2 fair value measurements.

In 2019, upon the achievement of the certain milestones, the Company sold 27,478,256 Series A-2 Units to investors, founders and employees in exchange for $31.6 million.

In March, 2020, with subsequent offerings through May 2020, the Company entered into a Series B Preferred Stock Purchase Agreement (the "Series B Agreement") with a total aggregate purchase price $145.2 million. Under the terms of the Series B Agreement, the Company agreed to sell 104,442,965 units of Series B Redeemable Convertible Preferred Units ("Series B Units") to investors at a price of $1.39028 per share.

The Series A and B Preferred Units, ("preferred units") have the following rights, preferences, and privileges:

Voting Rights—The holders of the preferred units are entitled to vote together as a single class and on an as converted to common units basis in accordance with each such holder's percentage interests. In addition, the preferred units holders shall have the right to vote separately as a series on any matter which would adversely alter or change the rights, powers or preferences of one series without a similar effect on the other series.

Conversion Rights—Each preferred unit is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration, into fully paid and nonassessable common units. The number of common units into which each preferred unit may be converted shall be determined by dividing the number of preferred units by their applicable original issue price, potentially subject to adjustment for anti-dilution provisions.

Each preferred unit is automatically converted into fully paid and nonassessable common units upon either the closing of the sale of common units to the public at a price of at least $2.08542 per unit in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50.0 million of gross proceeds to the Company, or at the occurrence of an event, specified in writing by the preferred units holders.

Dividends—The holders of preferred units may receive distributions declared and paid on the preferred units when determined by the Company's Board of Managers. The Company may not declare, pay or set aside any distributions on any common units unless the preferred units holders first receive, or simultaneously receive, a distribution on each outstanding preferred unit in an amount at least equal to the greater of 8% of the applicable original issue price of the preferred units, per year, from and after the date of the issuance on a non-cumulative basis of any preferred units or the pro-rata distribution that the preferred units holder would receive had they converted their preferred units into common units.

No dividends were declared or paid during the years ended December 31, 2020 and 2019.

Redemption Rights—The preferred units are only redeemable pursuant to a deemed liquidation event.

Anti-Dilution Provisions—If the Company makes adjustments to any class of units for dividends, splits, combinations or other similar events, or issues additional securities at a purchase price less than current conversion price for issued and outstanding preferred units, the preferred units conversion price shall be adjusted in accordance with a formula, as defined in the Company's Operating Agreement.

Liquidation—The preferred units have preferential rights with respect to any dissolution or liquidation of the Company and with respect to a sale of the Company. In the event of a dissolution, liquidation, or winding-up of the Company, the holders of the preferred units are entitled to receive, in preference to the holders of the common units and the incentive units, an amount equal to their original issue price. After payment of this preferential amount, remaining proceeds are distributed in accordance with a formula as defined in the Operating Agreement for the Company. This formula provides additional preferences to the preferred unit holders.

7. MEMBERS' DEFICIT

Common Units—In 2018, the Company issued 4,500,000 common units to its founders, including 3,375,000 restricted common units that vest over a four year period. In 2018, the Company also issued 1,200,000 restricted common units to the founders, pursuant to restricted share purchase agreements, which begin vesting upon achievement of certain performance conditions. These restricted common units vest into common units and therefore have been presented as common units within the consolidated statement of changes in redeemable convertible preferred units and members' deficit. Restricted common units issued to the founders vest 25% upon the 1-year anniversary of the Company initiating a clinical program through one of its controlled subsidiaries, monthly thereafter over the next 36 months. In 2019, it was determined that the performance condition of these restricted common units became probable, vesting started, and the units began being expensed over the vesting period. No other restricted common units were granted in 2020 or 2019. Each common unit entitles the holder to one vote on all matters submitted to a vote of the Company's members.

At December 31, 2020 and 2019, of the 4,500,000 common units issued to the founders, 2,812,500 and 1,968,750 of these restricted common units were fully vested, respectively, and the remaining 1,687,500 and 2,531,250 units vest over the remaining weighted average period of 1.30 and 2.33 years, respectively. During the years ended December 31, 2020 and 2019, the Company recognized $0.1 million of equity-based compensation expense relating to the issuance of these restricted common units for both years. As of December 31, 2020 and 2019, there was $0.2 million and $0.3 million of compensation expense relating to these restricted common units that remains to be amortized over the weighted average period of 1.30 and 2.33 years, respectively.

At December 31, 2020 and 2019, of the 1,200,000 restricted common units issued to the founders that were issued subject to performance-based vesting conditions, 375,000 and 0 of these restricted common units were fully vested, respectively, and the remaining 825,000 and 1,200,000 units are expected to vest over the remaining weighted average period of 2.70 and 3.71 years, respectively. During the years ended December 31, 2020 and 2019, the Company recognized equity-based compensation expense of $95,584 and $13,125, respectively, on these restricted common units. At December 31, 2020 and 2019, there was $0.1 million and $0.2 million of compensation expense that remained to be amortized over a weighted average period of 2.70 and 3.71 years, respectively.

Incentive Units—At December 31, 2020 and 2019, the Company has reserved 18,972,360 and 7,233,957 common units, respectively, for issuance to officers and other employees of the Company pursuant to the Rallybio Holdings, LLC 2018 Share Plan ("2018 Share Plan"). The reserve includes 1,200,000 restricted common units that were issued to the founders in 2018, discussed further below. At December 31, 2020 and 2019, 10,906,656 and 4,400,957 incentive units, respectively, remained available for future grants.

During the years ended 2020 and 2019, 5,232,704 and 1,423,000 incentive units were issued to employees of the Company, respectively. During the year ended December 31, 2020 and 2019, the Company recognized equity-based compensation expense of $0.5 million and $0.1 million, respectively, relating to the issuance of incentive units. At December 31, 2020 and 2019, there was $2.2 million and $0.5 million of equity-based compensation expense that remains to be amortized over a weighted average period of 3.22 and 3.36 years, respectively.

The assumptions that went into the option pricing models for determining the fair value of our incentive units granted in 2020 and 2019 are as follows:

	2020	2019
Expected volatility	95.00%	75.00%
Expected time to liquidity	1.5	3.0
Risk free interest rate	0.16%	1.74%
Expected dividend yield	0%	0%

The following table provides a summary of the activity under the 2018 Share Plan for incentive units granted to employees.

	INCENTIVE UNITS
Outstanding at December 31, 2018	210,000
Granted	1,423,000
Forfeited	—
Outstanding at December 31, 2019	1,633,000
Granted	5,232,704
Forfeited	—
Outstanding at December 31, 2020	6,865,704

At December 31, 2020 and 2019 6,865,704 and 1,633,000 incentive units granted under the 2018 Share Plan are outstanding and expected to vest, respectively. At December 31, 2020 and 2019, 495,182 and 112,292 incentive units are fully vested, respectively, and the remaining 6,370,522 and 1,520,708 units are expected to vest over a weighted average period of 3.12 and 3.49 years, respectively.

Equity-based compensation, including common and incentive units are classified in the consolidated statements of operations and comprehensive loss for years ended December 31, 2020 and 2019 as follows:

(in thousands)	2020	2019
Research and Development	$219	$ 29
General and Administrative	485	165
	$704	$194

8. INCOME TAXES

The combined provision for income taxes of tax paying subsidiaries of the Company is comprised of the following for the years ended December 31, 2020 and 2019.

(in thousands)	2020	2019
Current:		
Federal	$(15)	$ —
Income tax benefit	$(15)	$ —

The Company's effective income tax rates are different from the federal statutory tax rates in 2020 and 2019 predominantly due to the valuation allowance, tax credits, state taxes, and the federal net operating loss carryback tax benefit described below.

	2020	2019
U.S. federal statutory tax rate	21.0%	21.0%
State income taxes, net of federal income tax benefit	4.9%	—
Tax credits	8.0%	3.4%
Other	(0.2)%	2.6%
Valuation allowance	(33.6)%	(27.0)%
Effective Tax Rate	0.1%	—%

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, allows net operating losses incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act also eliminates the 80% of taxable income limitation allowing corporate entities to fully utilize net operating loss carryforwards to offset taxable income in 2018, 2019 and 2020. During 2019, two of the Company's wholly owned, subsidiaries generated federal net operating losses in 2019, and in December 2020, each subsidiary filed Forms 1139 to carryback these losses and offset all remaining taxable income in the 2018 tax year.

GAAP require balance sheet presentation to reflect when the assets are expected to be monetized. Forms 1139 were filed in December 2020, and a refund is expected within the next twelve months. The Company has reclassed the amount of tax-effected net operating losses, which have been utilized on the Form 1139 carryback claims, from a deferred tax asset to a current income tax receivable. Since the Company has provided a valuation allowance against the Company's deferred tax assets, this reclass has an impact on total income tax expense/(benefit).

On December 27, 2020 the Consolidated Appropriations Act, 2021 ("CAA") was signed into law. The CAA includes the COVID-related Tax Relief Act of 2020 ("COVID TRA"). The Company is continuing to assess the effect of the CAA and does not believe it will result in a material impact to the Company's income tax provision.

Deferred income taxes represent the tax effect of transactions that are reported in different periods for financial and tax reporting purposes. The combined temporary differences and carryforwards of each tax paying component of the Company that give rise to a significant portion of the deferred income tax benefits and liabilities are as follows at December 31, 2020 and 2019:

DEFERRED INCOME TAX ASSETS: (in thousands)	2020	2019
Net operating loss carryforwards	$ 10,675	$ 3,840
Amortization	1,823	1,883
Research and development credits	2,687	684
Other	135	22
Total deferred income taxes	15,320	6,429
Less valuation allowance	(15,320)	(6,429)
Net deferred income taxes	$ —	$ —

At December 31, 2020, the Company has approximately $38.7 million of federal net operating loss carryforwards, which do not expire, and approximately $38.8 million of state net operating loss carryforwards, which begin expiring in 2038.

The Company has provided a valuation allowance against the Company's deferred tax assets, since, in the opinion of management, based upon the history of losses by the Company; it is not more likely than not that the benefits will be realized. All or a portion of the remaining valuation allowance may be reduced in future years based on an assessment of earnings sufficient to fully utilize these potential tax benefits.

ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has no material uncertain tax positions that qualify for either recognition or disclosure in consolidated financial statements.

It is the Company's policy to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2020 and 2019, the Company has accrued no interest and penalties related to uncertain tax positions. The Company does not have any outstanding U.S. federal income tax or material state and local tax matters for periods through December 31, 2020. There are no federal or state and local income tax returns currently under examination.

9. INVESTMENT IN JOINT VENTURE

In July 2019, the Company through one its wholly-owned subsidiaries, entered into an agreement to establish a joint venture with Exscientia Limited ("Exscientia") to initiate early stage drug discovery on available small molecules and thereafter the future research, development, manufacture, sale and exploitation of any company-owned technology and compounds, including candidate compounds that result therefrom. In July 2019, the Company and Exscientia completed the formation of the joint venture entity, RE Ventures I, LLC, a limited liability corporation ("REV-I").

Each member received a 50% interest when the joint venture was created. Pursuant to the operating agreement, at inception of the joint venture the Company was obligated to initially contribute £0.5 million, or $0.6 million, to fund stage I development. The Company's initial investment in REV-I in the amount of $0.6 million at December 31, 2019 was unfunded and included in accrued expenses on the consolidated balance sheets. The unfunded obligation was subsequently funded in January 2020. In 2020, REV-I determined that the stage 1 development objective had been achieved. During 2020, the Company funded an additional $1.3 million associated with stage 2 development costs. The Company did not provide any additional financial support outside of capital contributions to REV-I during the years ended December 31, 2020 and 2019. The Company held a 50% interest in the joint venture as of December 31, 2020.

Based on management's analysis, the Company is not the primary beneficiary of REV-I since it does not have both (1) the power to direct the activities that most significantly impact the entity's economic performance which consists primarily of research and development activities and (2) the obligation to absorb the losses of the VIE or the right to receive the benefits from the VIE, which could be significant to the VIE. The research and development activities of REV-I are controlled by a management board under the joint control of the Company and Exscientia. All decisions are made by consensus with each member having one vote. Accordingly, the VIE is not consolidated in the Company's financial statements as of December 31, 2020. The Company accounts for its 50% interest under the equity method of accounting.

During the year ended December 31, 2020 and 2019, the Company recorded its allocable share of REV-I's losses, which totaled $1.5 million and $0.1 million, respectively, as a loss on investment in joint venture within the consolidated statements of operations and comprehensive loss. After recognition of its share of losses for the year, the carrying value and maximum exposure to risk of the REV-I investment as of December 31, 2020 and 2019, was $0.3 million and $0.5 million, respectively, which was recorded in investment in joint venture in the accompanying consolidated balance sheets.

10. COMMITMENTS AND CONTINGENCIES

Purchase Commitments—We enter contracts in the normal course of business with contract research organizations and other third-party vendors for clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consisting of payments for services provided or expenses incurred. As of December 31, 2020, and 2019 there were no amounts accrued related to termination charges.

Lease Commitments— In June 2019, the Company entered into a six-year lease to occupy office space located in New Haven, Connecticut, with the option to extend the initial term of the lease for one additional five year term. Pursuant to the lease the Company was obligated to pay for its share of costs related to the build-out of new space. All costs associated with the build-out of the new space have been capitalized as leasehold improvements and are being amortized over the life of the lease. In October 2020, the Company modified the existing New Haven lease agreement and leased additional space that coincides with the original lease term expiration date.

Rent expense was $87,833 and $42,429 for the years ended December 31, 2020 and 2019, respectively.

Future minimum annual lease payments are as follows:

YEAR ENDING DECEMBER 31 (in thousands)	
2021	$ 83
2022	109
2023	112
2024	115
2025	88
Thereafter	—
	$507

11. NET LOSS PER COMMON UNIT

Basic and diluted loss per common unit were calculated as follows:

NET LOSS PER COMMON UNIT (in thousands except share and per share amounts)	2020	2019
Net loss	$ (26,447)	$ (17,563)
Net loss attributable to common units-basic and diluted	(26,447)	(17,563)
Weighted average number of common units outstanding, basic and diluted	2,659,187	1,715,164
Net loss per common unit	$ (9.95)	$ (10.24)

The following common stock equivalents have been excluded from the calculations of diluted loss per common unit because their inclusion would have been antidilutive:

ANTIDILUTIVE UNITS	2020	2019
Unvested restricted common units	2,512,500	3,731,250
Incentive units	6,865,704	1,633,000
Series A Preferred Units, as converted	33,478,255	33,478,255
Series B Preferred Units, as converted	104,442,965	—
Total	147,299,424	38,842,505

12. SUBSEQUENT EVENTS

The Company evaluated all material subsequent events through April 27, 2021, the date the consolidated financial statements were available to be issued. The following events occurred subsequent to December 31, 2020.

In January 2021, the Board of Managers of the Company approved an increase in the employee stock plan incentive pool shares available by an additional 4,000,000 common units, for issuance to officers, managers, employees and consultants of the Company pursuant to the 2018 Share Plan.

Shares

Common Stock

PRELIMINARY PROSPECTUS

Jefferies **Cowen** **Evercore ISI**

, 2021

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the Nasdaq Global Market listing fee:

ITEM	AMOUNT TO BE PAID
SEC registration fee	$ *
FINRA filing fee	650
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102(b)(7) of the DGCL, we plan to include in our amended and restated certificate of incorporation a provision to eliminate the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors, subject to certain exceptions. In addition, our amended and restated certificate of incorporation and bylaws will provide that we are required to indemnify our officers and directors under certain circumstances, including those circumstances in which indemnification would otherwise be discretionary, and we are required to advance expenses to our officers and directors as incurred in connection with proceedings against them for which they may be indemnified, in each case except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145(a) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

Section 145(b) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer,

employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

We have entered into indemnification agreements with our directors and, prior to the completion of this offering, intend to enter into indemnification agreements with certain of our officers. These indemnification agreements will provide broader indemnity rights than those provided under the DGCL and our amended and restated certificate of incorporation. These indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement will provide that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act.

We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2018. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(a) Issuances of units

In April 2018, certain investors purchased an aggregate of 5,549,999 of our Series A-1 preferred units for an aggregate of $5,549,999 at a price of $1.00 per unit.

In April 2018, we issued an aggregate of 450,000 Series A-1 preferred units to the Founders in exchange for their capital contributions of convertible debt for an aggregate of $450,000.

In April 2019, certain investors purchased an aggregate of 7,826,083 of our Series A-2 preferred units and our Founders and certain employees purchased an aggregate of 521,740 of our Series A-2 preferred units for an aggregate of $9,599,996 at a price of $1.15 per unit.

In July 2019, certain investors purchased an aggregate of 8,695,652 of our Series A-2 preferred units for $10,000,000 at a price of $1.15 per unit.

In October 2019, certain investors purchased an aggregate of 10,434,781 of our Series A-2 preferred units for $11,999,998 at a price of $1.15 per unit.

In March 2020, certain investors purchased an aggregate of 61,457,763 of our Series B preferred units for approximately $91,104,988 at a price of $1.4824 per unit.

In April 2020, certain investors purchased an aggregate of 1,416,621 of our Series B preferred units for approximately $2,099,999 at a price of $1.4824 per unit.

In May 2020, certain investors purchased an aggregate of 37,402,537 of our Series B preferred units for approximately $51,999,999 at a price of $1.3903 per unit.

Also in May 2020, investors who purchased Series B preferred units in March 2020 and April 2020 received an aggregate of 4,166,044 additional Series B preferred units, for no additional consideration, to provide such investors with the benefit of the lower purchase price paid by investors at the May 2020 closing in accordance with the terms of the Series B Purchase Agreement.

Through March 31, 2021, we have issued an aggregate of 4,500,000 common units, for a purchase price of $0.79 per unit, which was paid through the contribution of the holders' equity interests in a subsidiary of the LLC Entity.

(b) Grants

Through March 31, 2021, we have granted an aggregate of 19,934,704 incentive units, with a grant date fair value range of $0.10–$ per unit, to employees, directors and consultants pursuant to the 2018 Share Plan.

Through March 31, 2021, we have granted the Founders an aggregate of 1,200,000 restricted shares (common), under the 2018 Plan, with a grant date fair value of $0.15 per unit.

The issuances of the above securities were exempt either pursuant to Rule 701, as transactions pursuant to a compensatory benefit plan, or pursuant to Section 4(a)(2), as transactions by an issuer not involving a public offering.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1*	Form of Underwriting Agreement.
2.1*	Form of Merger Agreement.
3.1*	Form of Amended and Restated Certificate of Incorporation of the Registrant (to be effective prior to the consummation of this offering).
3.2*	Form of Amended and Restated Bylaws of the Registrant (to be effective prior to the consummation of this offering).
4.1*	Specimen stock certificate evidencing shares of common stock.
4.2*	Form of Registration Rights Agreement, among the Registrant and certain of its stockholders, to be in effect immediately prior to completion of this offering.
5.1*	Opinion of Ropes & Gray LLP.
10.1+	Asset Purchase Agreement, by and between Rallybio IPA, LLC and Prophylix AS, dated June 28, 2019.
10.2+	Asset Transfer Agreement, by and between Swedish Orphan Biovitrum AB (PUBL) and IPC Research, LLC, dated March 15, 2019.
10.3+	Product License Agreement, by and between Affibody AB and Swedish Orphan Biovitrum AB (PUBL), dated March 9, 2012, and assigned to IPC Research, LLC on March 15, 2019.
10.4+	Amendment No. 1 to Product License Agreement, by and between Affibody AB and Swedish Orphan Biovitrum AB (PUBL), dated January 1, 2018, and assigned to IPC Research, LLC on March 15, 2019.
10.5+	Amendment No. 2 to Product License Agreement, by and between Affibody AB and IPC Research, LLC, dated December 22, 2020.
10.6#*	Form of Indemnification Agreement, between the Registrant and each of its directors and executive officers.
10.7#	Rallybio Holdings, LLC 2018 Share Plan, as amended.
10.8#*	2021 Equity Incentive Plan.
10.9#*	2021 Cash Incentive Plan.
10.10#*	2021 Employee Stock Purchase Plan.
21*	List of Subsidiaries of the Registrant.
23.1*	Consent of Deloitte & Touche LLP independent registered public accounting firm.
23.2*	Consent of Ropes & Gray LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).

* To be filed by amendment.

\# Indicates management contract or compensatory plan.

\+ Portions of this exhibit (indicated by asterisks) have been redacted because they are both not material and the registrant customarily and actually treats such information as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New Haven, Connecticut, on , 2021.

RALLYBIO HOLDINGS, LLC

By: _____
Martin W. Mackay, Ph.D.
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Martin W. Mackay and Jeffrey M. Fryer, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, the registration statement on Form S-1 filed herewith, and any and all pre-effective and post-effective amendments to said registration statement, and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, in connection with the registration under the Securities Act of 1933, as amended, of equity securities of the Company, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

SIGNATURE	TITLE	DATE
Martin W. Mackay, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	, 2021
Jeffrey M. Fryer, CPA	Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	, 2021
Helen M. Boudreau	Director	, 2021
Rob Hopfner, R.Ph., Ph.D.	Director	, 2021
Ronald M. Hunt	Director	, 2021
Lucian Iancovici, MD	Director	, 2021
Kush M. Parmar, MD, Ph.D.	Director	, 2021
Timothy M. Shannon, MD	Director	, 2021
Paula Soteropoulos	Director	, 2021

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

ASSET PURCHASE AGREEMENT

Dated as of June 28, 2019

between

RALLYBIO IPA, LLC

and

PROPHYLIX AS

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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement, dated as of June 28, 2019 (the "**Execution Date**") (as amended or otherwise modified, this "**Agreement**") is between **RALLYBIO IPA, LLC,** a Delaware limited liability company ("**Rallybio**"), and **PROPHYLIX AS**, a Norwegian company with registration number 920 056 261 ("**Prophylix**") (each of the foregoing individually a "**Party**" and collectively the "**Parties**").

RECITALS

WHEREAS, Prophylix desires to sell, transfer, assign and deliver to Rallybio, and Rallybio desires to purchase, acquire, assume and accept from Prophylix, all of Prophylix's rights, title and interest in, to and under all assets, properties and rights related to the worldwide research, development, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products; and

WHEREAS, the Parties hereto desire to make certain representations, warranties, covenants and agreements in connection with the transactions described above and also to prescribe various conditions to the consummation of the transactions described above.

AGREEMENT

NOW THEREFORE, in consideration of the premises and mutual promises herein made, and in consideration of the representations, warranties and covenants herein contained, Rallybio and Prophylix hereby agree as follows:

1. DEFINITIONS; CERTAIN RULES OF CONSTRUCTION.

1.1. Certain terms used in this Agreement are defined in Exhibit 1 to this Agreement.

1.2. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article, Exhibit, Appendix or Schedule means a Section or Article of, or Schedule, Exhibit or Appendix to this Agreement, unless another agreement is specified, (b) the word "including" (in its various forms) means "including without limitation," (c) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulation, in each case as amended or otherwise modified from time to time, (d) words in the singular or plural form include the plural and singular form, respectively, (e) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, (f) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if," (g) the words "will" and "shall" shall be interpreted to have the same meaning, and (h) references to "$" shall mean U.S. dollars.

2. THE ACQUISITION.

2.1. Purchase and Sale of the Acquired Assets. Prophylix agrees to sell, transfer, convey, assign and deliver to Rallybio, and Rallybio agrees to purchase from Prophylix at the Closing, subject to and upon the terms and conditions contained herein, free and clear of any

Liens, all of Prophylix's right, title and interest in, to and under all assets, properties and rights (whether intangible, documents, personal or mixed, whether fixed, contingent or otherwise and including all Intellectual Property contained therein or related thereto) related to the worldwide research, development, manufacture, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products other than the Excluded Assets (collectively, the "**Acquired Assets**"). The Acquired Assets include:

(a) *Regulatory Filings*. All Governmental Authorizations relating to the Products, including the Governmental Authorizations listed on Schedule 2.1(a), copies of all correspondence with any Governmental Authority relating thereto, and copies of all material internal memoranda, communications and reports relating to meetings or teleconferences with such Governmental Authority (collectively, the "**Transferred Governmental Authorizations**");

(b) *Data and Results*. All clinical, non-clinical and technical development investigation data and documentation (including protocols, investigator brochures, final reports, safety data, raw data, batch records, data tables, data files and summaries from all clinical, non-clinical and technical development investigations, and all case report forms) relating to the Products;

(c) *Acquired Intellectual Property*. All Intellectual Property relating to the Products (collectively, the "**Acquired Intellectual Property**"), including all Patents, Know-How, Trademarks, and domain name registrations listed on Schedule 2.1(c);

(d) *Materials*. All materials, including existing drug product and drug substance, plasma banks and cell banks, including those listed on Schedule 2.1(d);

(e) *Assumed Contracts*. The written Contractual Obligations that are listed on Schedule 2.1(e) (collectively, the "**Assumed Contracts**");

(f) *Books and Records*. Prophylix's books, records, customer and other reports, files and papers, correspondence and other documents, invoices, whether in hard copy or computer or other electronic format, including manuals and data, in each case, related to the Products, other than (i) any books, records or other materials originals of which Prophylix is required by Legal Requirement to retain (in which case copies of which, to the extent permitted by Legal Requirement, will be made available to Rallybio at Rallybio's reasonable request) and (ii) personnel, medical and employment records for employees and former employees of Prophylix;

(g) *Claims*. All rights, privileges, Claims and Actions (regardless of whether or not such Claims or Actions have been asserted by Prophylix) arising out of or relating to the ownership, performance or operation of the Acquired Assets or the Products after the Closing or the assumption of the Assumed Liabilities; and

(h) *Other Assets*. The other assets set forth on Schedule 2.1(h).

2.2. Excluded Assets. Prophylix hereby retains and shall not transfer, assign, convey or otherwise transfer to Rallybio any of the assets, properties or rights set forth on Schedule 2.2 (collectively, the "**Excluded Assets**").

2.3. Third Party Consents. To the extent that Prophylix's rights under any Governmental Authorization, Contractual Obligation or Permit constituting an Acquired Asset, or any other Acquired Asset, may not be assigned to Rallybio without the consent of another Person which has not been obtained, this Agreement shall not constitute an agreement to assign the same if an attempted assignment would constitute a breach thereof or be unlawful, and Prophylix, at its expense, shall use its commercially reasonable efforts to obtain any such required consent(s) as promptly as possible. If any such consent shall not be obtained or if any attempted assignment would be ineffective or would impair Rallybio's rights under the Acquired Asset in question so that Rallybio would not in effect acquire the benefit of all such rights, Prophylix, to the maximum extent permitted by law and the Acquired Asset, shall act after the Closing as Rallybio's agent in order to obtain for it the benefits thereunder and shall cooperate with Rallybio in any other reasonable arrangement designed to provide such benefits to Rallybio. Notwithstanding any provision in this Section 2.3 to the contrary, Rallybio shall not be deemed to have waived its rights under Section 7.8 hereof unless and until Rallybio either provides written waivers thereof or elects to proceed to consummate the transactions contemplated by this Agreement at Closing.

2.4. Assumed Liabilities. At the Closing, Rallybio will assume in accordance with their respective terms only, the following specified obligations and liabilities of Prophylix (collectively, the "**Assumed Liabilities**"), but no others and excluding, for the avoidance of doubt, the Excluded Liabilities set forth in Section 2.5:

(a) all Liabilities under or relating to the Acquired Assets or the Products arising from circumstances or events arising or occurring after the Closing;

(b) a portion of the Sign-On Fee as set forth in Section 7.7 below;

(c) all Liabilities as holder of the Governmental Authorizations arising from circumstances or events arising or occurring after the Closing;

(d) all Liabilities arising out of or related to the research, development, manufacture, use, storage, sale or other disposition of the Products after the Closing; and

(e) all Liabilities arising out of or relating to lawsuits and claims arising from the development, nonclinical and clinical testing, commercialization, manufacture, storage, packaging, import, marketing, labeling, pricing, distribution, sale or use of the Products or the use of the Acquired Assets, in each case, by or on behalf of Rallybio or its Affiliates after the Closing.

Rallybio is not assuming, and shall not be deemed to have assumed by virtue of acquiring the Acquired Assets or the Assumed Liabilities, any obligations or Liabilities of Prophylix other than the Assumed Liabilities specifically described above. No assumption by Rallybio of any of the Assumed Liabilities shall relieve or be deemed to relieve Prophylix from any Contractual Obligation or Liability under this Agreement with respect to any representations or warranties made by Prophylix to Rallybio. For avoidance of doubt, this Section 2.4 is solely intended to identify and provide for the assumption by Rallybio of those Liabilities of Prophylix that are specifically assumed by Rallybio hereunder and which, but for such assumption, would remain Liabilities of Prophylix.

2.5. Excluded Liabilities. Notwithstanding anything in this Agreement to the contrary, Rallybio is not assuming (and Prophylix will satisfy and perform when due, and, on the terms and subject to the conditions of Section 10, will hold Rallybio harmless with respect to) any Liabilities of Prophylix other than the Assumed Liabilities (the "**Excluded Liabilities**"). For the avoidance of doubt, the Excluded Liabilities include:

(a) all Liabilities for or in respect of (i) any and all Taxes (or the non-payment thereof) of Prophylix or its Affiliates whether or not relating to Prophylix or any of its Affiliates and whether or not incurred prior to the Closing, (ii) any and all Taxes of any member of an affiliated, consolidated, combined or unitary group of which Prophylix or its Affiliates is, was or will be a member, (iii) any and all Taxes of any Person imposed on Rallybio or any Affiliate thereof as a transferee of the Acquired Assets, (iv) any Liability for Taxes allocated to Prophylix pursuant to Section 11.2 or Section 11.4 and (v) any other Taxes of Prophylix (or any member or Affiliate of Prophylix) of any kind or description (including any Liability for Taxes of Prophylix (or any member or Affiliate of Prophylix)) that becomes a Liability of Rallybio under any common law doctrine of de facto merger or transferee or successor liability or otherwise by operation of contract or Legal Requirement;

(b) all Liabilities of Prophylix and its Affiliates under or relating to the Acquired Assets or the Products arising from circumstances or events arising or occurring on or prior to the Closing;

(c) all Liabilities arising out of or related to the research, development, manufacture, use, storage, sale or other disposition of the Products on or prior to the Closing;

(d) all Liabilities and Contractual Obligations under or relating to any contract or asset not assigned to Rallybio;

(e) all Liabilities of Prophylix arising from or relating to Prophylix's employees, consultants, employee benefit plans or any employment or worker-related Legal Requirements;

(f) all Liabilities arising from or relating to the Excluded Assets; and

(g) all Liabilities arising from or relating to the operation of Prophylix's businesses that do not relate to the Acquired Assets.

2.6. Prepaid Patent Expenses. Prior to the Execution Date, Prophylix shall deliver to Rallybio any and all documentation related to pre-paid Patent prosecution expenses incurred with respect to the Prophylix Patents, as reflected in Schedule 2.6, relating to the period after Closing (the "**Prepaid Patent Expenses Amount**"). The Prepaid Patent Expenses Amount shall be reimbursed by Rallybio by wire transfer of immediately available funds to an account designated in writing by Prophylix to Rallybio.

2.7. Closing. The closing of the Acquisition (the "**Closing**") shall take place at 9:00 am Eastern Daylight Savings Time on a date to be specified by Prophylix and Rallybio, which shall be no later than two (2) Business Days following the date of satisfaction or waiver of all of the conditions set forth in Sections 7 and 8 that are susceptible to satisfaction prior to the Closing Date, at the offices of Wiggin and Dana, LLP, 450 Lexington Ave, New York, NY 10017, unless another date or place is agreed to in writing by Prophylix and Rallybio. As of the Execution Date, it is the intention of the Parties for the Closing to occur on June 28, 2019.

2.8. Closing Deliverables.

2.8.1. At the Closing, Prophylix shall deliver to Rallybio the following:

(a) the Bill of Sale and Assignment and Assumption Agreement duly executed by Prophylix;

(b) the Patent Assignment duly executed by Prophylix;

(c) the IPR Assignment Agreement;

(d) [Intentionally Omitted];

(e) such other customary instruments of transfer, assumption, filings or documents, in form and substance reasonably satisfactory to Rallybio, as may be required to give effect to this Agreement and the Contemplated Transactions; and

(f) IRS Form W- 8BEN.

2.8.2. At the Closing, Rallybio shall deliver to Prophylix the following:

(a) the Bill of Sale and Assignment and Assumption Agreement duly executed by Rallybio;

(b) [Intentionally Omitted]; and

(c) evidence of the initiation by Rallybio or its designee of the wire transfers of (i) the Closing Payment to Prophylix, in accordance with Section 3.1, and (ii) the [***] Manufacturing Fee, in accordance with Section 3.2.

2.9. Withholding. Rallybio will be entitled to deduct and withhold from the Purchase Price all Taxes that Rallybio may be required to deduct and withhold under any Legal Requirement, provided that, following the Closing, before making any such deduction or withholding, Rallybio shall give Prophylix written notice of its intention to make such deduction or withholding a commercially reasonable period of time in advance of such deduction or withholding as is required in order for such recipient to establish reduction of or relief from such deduction or withholding. To the extent Taxes withheld from payments made hereunder, such withheld amounts will be treated as amounts received by the Party with respect to which such Taxes were withheld for all purposes under this Agreement. Each Party will use commercially reasonable efforts to cooperate with and assist the other Party (at the other Party's sole expense) in claiming Tax refunds, deductions or credits at such other Party's request and will cooperate with the other Party (at the other Party's sole expense) to minimize any withholding Tax as permitted by applicable Legal Requirements.

2.10. Additional Matters. At and after the Closing, at Rallybio's written request, Prophylix shall and shall cause its Representatives to execute all documents and perform all acts reasonably deemed necessary by Rallybio to evidence Rallybio's ownership of the Acquired Assets. Without limiting the foregoing, at and after the Closing, the officers and managers of Rallybio shall be authorized to execute and deliver, in the name and on behalf of Prophylix, any bills of sale, assignments or assurances and to take and do, in the name and on behalf of Prophylix, any other actions and things to vest, perfect or confirm of record or otherwise in Rallybio, any and all right, title and interest in, to and under any of the Acquired Assets. Following the Closing, Prophylix shall promptly deliver to Rallybio copies of all documents included in the Acquired Assets in a mutually acceptable electronic format. At and after the Closing, at Rallybio's written request and expense, Prophylix shall reasonably assist Rallybio in prosecuting, obtaining, registering, maintaining, defending and enforcing the Acquired Intellectual Property, including, in the event of a defense or enforcement of the Acquired Intellectual Property, making Prophylix's relevant personnel reasonably available to cooperate with any litigation.

3. PURCHASE PRICE

3.1. Purchase Price. Rallybio agrees to assume the Assumed Liabilities and agrees to pay to Prophylix an aggregate amount (the "**Purchase Price**") consisting of: (a) One Million Two Hundred Forty-Two Thousand and Five Hundred U.S. Dollars ($1,242,500), which is equal to One Million Three Hundred Thousand U.S. Dollars ($1,300,000) less Prophylix's allocable portion of the Sign-On Fee as set forth in Section 7.7 below (the "**Closing Payment**") to be paid within three (3) Business Days following the Closing Date to an account designated in writing by Prophylix to Rallybio; (b) payment of the milestone amounts as provided in Section 3.3 below; (c) payment of the royalty payments as provided in Section 3.4 below; and (d) [***] of the proceeds received, on an after-tax basis, of the Priority Review Voucher as provided in Section 3.5 below. For clarity, the Purchase Price does not include any amounts paid by Rallybio to Prophylix for the [***] Manufacturing Fee or the Prepaid Patent Expenses Amount.

3.2. Manufacturing Fee Reimbursement. Reimbursement or direct payment, as the case may be, in cash of up to One Million Seven Hundred and Fifty Thousand U.S. Dollars ($1,750,000) paid or to be paid in 2019 by Prophylix to [***] ("**[***]**") in relation to the manufacture [***]. For purposes of this Agreement, the "**[***] Manufacturing Fee**" shall mean amounts paid or to be paid by Prophylix to [***] for [***] on terms previously disclosed in writing by Prophylix to Rallybio. It is contemplated the [***] Manufacturing Fee shall be paid in several tranches with Five Hundred Thousand U.S. Dollars ($500,000) to be paid [***] and the balance of approximately One Million Two Hundred Thousand U.S. Dollars ($1,200,000) to be paid in June and July 2019. In due time prior to the Closing Date, Prophylix shall provide Rallybio with an invoice and reasonable supporting documentation for the part of the [***] Manufacturing Fee already paid by Prophylix, which shall be paid by Rallybio within three (3) Business Days following the Closing Date to an account designated in writing by Prophylix to Rallybio. Any part of the [***] Manufacturing Fee becoming due after Closing shall be paid by Rallybio to [***] directly.

3.3. Milestone Payments

3.3.1. Milestone Payments. Rallybio agrees to make the following payments to Prophylix at such time, if any, as any one or more of the following milestones is achieved.

Milestone	U.S. Dollars
1. [***]	$ [***]
2. [***] ("**Milestone 2**")	$ [***]
3. [***] ("**Milestone 3**")	$ [***]
4. [***]	$ [***]
5. [***]	$ [***]

3.3.2. Timing. Rallybio shall notify Prophylix of the achievement of each milestone promptly following achievement of such milestone, setting forth the clause in Section 3.3.1 giving rise to such payment obligation and the amount thereof. Rallybio shall make payment of such amount within forty-five (45) days of achievement of each milestone. All payments shall be made in cash by wire transfer of immediately available funds in United States Dollars to the credit of such bank account designated by Prophylix for the Closing Payment, or such account as may be otherwise designated, from time to time, by Prophylix in writing to Rallybio.

3.3.3. Single Payment Obligation. It is understood that each of the milestone payments above in Section 3.3.1 will not be made more than once, on the first instance only of either Product (NAITgam or the T1 Antibody) attaining such milestone.

3.4. Royalties

3.4.1. Rallybio agrees to pay royalties to Prophylix based on the following table:

Annual Net Sales	**Royalty Rate**	
	Products containing NAITgam	**Products containing T1 Antibody**
Up to $[***]	[***]	[***]
Greater than $[***] up to $[***]	[***]	[***]
Greater than $[***]	[***]	[***]

3.4.2. Calculation. Royalties payable to Prophylix are incremental rates that apply to the aggregated annual Net Sales of the indicated Products in the Territory during the Royalty Term, as indicated for each applicable rate. To illustrate by way of example, if Net Sales of a Product containing NAITgam in the Territory during the Royalty Term in a calendar year were $[***], then Rallybio will pay a royalty of [***] of $[***], plus [***] of $[***], plus [***] of $[***] for a total of $[***]. In the event that Rallybio reports Net Sales from Products containing NAITgam, as well as Products containing a T1 Antibody, the Net Sales of Products containing NAITgam will be counted first towards the sales level bracket identified above in determining the applicable royalty rate for such Products containing NAITgam. The Net Sales from Product containing a T1 Antibody will then be subsequently applied towards the sales level bracket identified above, after applying the Net Sales of Products containing NAITgam, in determining the applicable royalty rate for the Net Sales of Products containing a T1 Antibody. To illustrate by way of example, if Net Sales of a Product in the Territory during the Royalty Term in a calendar year were $[***] of which $[***] was from NAITgam and $[***] was from a Product containing a T1 Antibody, then Rallybio will pay a royalty of [***] of $[***], plus [***] of $[***], plus [***]% of $[***] for a total of $[***].

3.4.3. Royalty Term. Rallybio's obligations to pay royalties under this Section 3.4 shall terminate on a country-by-country and Product-by-Product basis at the later of (a) expiration of the last-to-expire Valid Claim of a Prophylix Patent covering the Product, (b) expiration of regulatory exclusivity, and (c) ten (10) years following First Commercial Sale of such Product in such country (the "**Royalty Term**"); *provided*, that if there is a challenge to the enforceability of the Prophylix Patents or royalty payments following the expiration of all Valid Claims of the Prophylix Patents in any country that is reasonably likely to result in the Prophylix Patents no longer being enforceable, as mutually determined by Rallybio and Prophylix, then the royalty rate will be reduced by [***] for the balance of the Royalty Term in such country.

3.4.4. Reporting and Payments. Within forty-five (45) days of the end of each applicable calendar quarter following the First Commercial Sale of any Product, Rallybio shall provide Prophylix with a written statement showing, on a country-by-country basis, Net Sales in the Territory and the amount of royalties due on such Net Sales in countries or regions in the Territory during the Royalty Term ("**Royalty Report**"). Concurrent with the submission of a Royalty Report for each such quarter, Rallybio shall pay Prophylix all royalties due in respect of such quarter. All payments shall be made in cash by wire transfer of immediately available funds in United States Dollars to the credit of such bank account designated by Prophylix for the Closing Payment, or such account as may be otherwise designated, from time to time, by Prophylix in writing to Rallybio.

3.4.5. Offset for Third Party Royalties. Except for any royalty payments made by Rallybio to any manufacturer negotiated by Rallybio as part of its payment for the manufacture of any Product, Rallybio shall be entitled to offset against any royalties due to Prophylix (a) [***] of any royalties for NAITgam Products paid by Rallybio or any Affiliate or licensee of Rallybio under any license to Intellectual Property owned or controlled by a Third Party that is required to develop, make, use sell, offer for sale supply or import, and (b) [***] of any royalties for T1 Antibody Products paid by Rallybio or any Affiliate or licensee of Rallybio under any license to Intellectual Property owned or controlled by a Third Party that is required to develop, make, use sell, offer for sale supply or import and relates to composition or matter or use of the Product, in each case, including in connection with the settlement of a Patent infringement claim, court or other similar binding order or ruling requiring any payments, including the payment of a royalty to a Third Party Patent holder in respect of sales of any Product; *provided* that the Royalty Payments otherwise due to Prophylix on account of Net Sales of Products shall not be reduced by more than [***]. Rallybio shall carry forward any offsets permitted under this Section 3.4.5 into future payment periods until such time as all such offsets have been applied. In addition, and notwithstanding anything to the contrary herein, Rallybio shall be entitled to offset against royalties due to Prophylix [***]of any royalties that may become due under the Tromsø License or IPR Assignment Agreement.

3.4.6. Records of Sales. Rallybio, its Affiliates and licensees shall keep for three (3) years from the end of each calendar year complete and accurate records of their sales of Products in sufficient detail to allow the accruing milestone and Royalty Payments to be determined accurately. Prophylix shall have the right for a period of one (1) year after receiving any report or statement with respect to milestone and Royalty Payments due and payable to appoint an independent certified public accountant reasonably acceptable to Rallybio to inspect the relevant records to verify such report or statement. Such inspection right shall not be exercised more than once in any calendar year. Rallybio shall reasonably cooperate with the appointed accountant in the carrying out of any audits, and shall make available for inspection books, records and documents in its possession relevant to Rallybio's payment obligations under this Agreement. Prophylix agrees to hold in strict confidence all information concerning milestone and Royalty Payments and reports, and all information learned in the course of any audit or

inspection (and not to make copies of such reports and information). The results of each inspection, if any, shall be binding on both Parties. Prophylix shall pay for such inspections, except that in the event there is any upward adjustment in aggregate Royalty Payments payable for any year shown by such inspection of more than [***] of the amount paid, Rallybio shall pay for such inspection. Rallybio shall include in each license agreement entered into by it with respect to the Products a provision requiring the licensee to keep and maintain adequate records of sales made pursuant to such license agreement and to grant access to such records in accordance with this Section 3.4.6. If the audit uncovers that Rallybio has paid less than what is required under this Agreement, then Rallybio shall make an adjusting payment to Prophylix in an amount equal to such shortfall. Any adjusting payments to be made by Rallybio pursuant to this Section 3.4.6 shall be made no later than five (5) Business Days following the result of the inspection, to an account designated in writing by Prophylix to Rallybio. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods. Prophylix agrees that all information subject to review under this Section 3.4.6 or under any license is confidential and that Prophylix shall retain and cause their representative to retain all such information in confidence.

3.5. Priority Review Voucher. In the event that the FDA grants a Priority Review Voucher in connection with the Regulatory Approval of a Product, Rallybio will pay Prophylix [***] of the proceeds received net of taxes, [***] in an arms-length transaction to a Third Party within twelve (12) months of receipt. Rallybio may, in its sole discretion, elect whether or not to sell the Priority Review Voucher and the price for the sale of such Voucher. If Rallybio does not sell the Priority Review Voucher to a Third Party within twelve (12) months, then Rallybio will pay Prophylix [***] of the fair market value. The fair market value shall be determined in accordance with the formula set forth in Schedule 3.5.

4. REPRESENTATIONS AND WARRANTIES REGARDING PROPHYLIX.

In order to induce Rallybio to enter into and perform this Agreement and to consummate the Acquisition, Prophylix hereby represents and warrants to Rallybio that, except as expressly set forth in the Disclosure Schedule, the statements contained in this Section 4 are true and correct. The Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered sections and subsections specifically referenced in this Section 4.

4.1. Organization. Prophylix is duly organized, validly existing and in good standing under the laws of Norway, with registration number 920 056 261. Prophylix is duly qualified to do business and in good standing in each jurisdiction in which Prophylix's ownership, leasing or operation of the Acquired Assets makes such qualification necessary. From November 27, 2017 until August 13, 2018, Prophylix was registered under the name "Prophylix Pharma II AS," and from August 13, 2018 until September 10, 2018, Prophylix was registered under the name "Prophylix Pharma AS." On September 10, 2018, Prophylix changed its name to "Prophylix AS." In addition, effective August 13, 2018, Prophylix and Prophylix Pharma AS, a former Norwegian company with registration number 993 218 162 (the "**Merged Entity**"), entered into a merger, pursuant to which Prophylix was the surviving company and the Merged Entity was liquidated (the "**Merger**"). Upon the consummation of the Merger, Prophylix assumed all of the assets and liabilities of the Merged Entity and the Merged Entity thereafter ceased to exist.

4.2. Power and Authorization.

4.2.1. Contemplated Transactions. The execution, delivery and performance by Prophylix of this Agreement and the consummation of the Contemplated Transactions are within the corporate power and authority of Prophylix and have been duly authorized by all necessary action on the part of Prophylix. This Agreement has been duly executed and delivered by Prophylix and, assuming the due authorization, execution and delivery by each of the other Parties hereto, is a legal, valid and binding obligation of Prophylix, Enforceable against Prophylix in accordance with its terms subject to the effects of bankruptcy, insolvency or other Legal Requirements of general application affecting the enforcement of creditor rights.

4.2.2. Conduct. Prophylix has all requisite limited liability company power and authority necessary to research, develop, manufacture, make, use, sell, offer for sale, import, export and otherwise exploit the Products as currently conducted by Prophylix and to enter into and perform its obligations under this Agreement, the Transfer Agreements, and to consummate the Contemplated Transactions.

4.3. Authorization of Governmental Authorities. Other than the transfer of Government Authorizations in accordance with Section 6.8, no action by (including any authorization, consent or approval), or in respect of, or filing with, any Governmental Authority is required for, or in connection with, the valid and lawful (a) authorization, execution, delivery and performance by Prophylix of this Agreement or (b) the consummation of the Contemplated Transactions by Prophylix.

4.4. Non-contravention. Neither the execution, delivery and performance by Prophylix of this Agreement nor the consummation of the Contemplated Transactions will:

(a) violate any Legal Requirement applicable to Prophylix;

(b) result in a breach or violation of, or default under, right to accelerate payment under or obligation to make any payment pursuant to or loss of material rights under, or modify or terminate (i) any Assumed Contract or (ii) any other material Contractual Obligation of Prophylix;

(c) contravene, conflict with or result in any limitation on Prophylix's right, title or interest in or to any Products Intellectual Property or its ability to transfer, assign or convey all such Products Intellectual Property to Rallybio;

(d) require any action by (including any authorization, consent or approval) or in respect of (including notice to), any Person under any Contractual Obligation of Prophylix;

(e) result in the creation or imposition of a Lien upon, or the forfeiture of, any Acquired Asset; or

(f) result in a breach or violation of, or default under, Prophylix's Organizational Documents.

The sale, transfer, conveyance, assignment and delivery of the following assets to Rallybio hereunder will not violate the terms of any agreement with any Third Party or give rise to any obligation to pay compensation (including milestones or royalties) to a Third Party: (A) the Governmental Authorizations listed on Schedule 2.1(a), (B) the Patents listed on Schedule 2.1(c), (C) the assets and properties listed on Schedule 2.1(d), (D) the Contractual Obligations listed on Schedule 2.1(e), and (E) to Prophylix's Knowledge, any other assets, properties or rights otherwise includable in the Acquired Assets.

4.5. Financial Statements. Complete copies of the audited financial statements consisting of the balance sheet of Prophylix as at December 31, 2018 and the related statements of income and retained earnings, stockholders' equity and cash flow for the periods then ended (the "**Financial Statements**") have been delivered to Rallybio. The Financial Statements have been prepared in accordance with the rules regarding small companies as set out in the Norwegian Accounting Act of 1998 applied on a consistent basis throughout the period involved. The Financial Statements are based on the books and records of Prophylix, and fairly present the financial condition of Prophylix as of the respective dates they were prepared and the results of its operations for the periods indicated. Prophylix maintains a standard system of accounting established and administered in accordance with the rules regarding small companies as set out in the Norwegian Accounting Act of 1998.

4.6. Absence of Certain Developments. Since December 31, 2018:

(a) no Acquired Asset has become subject to any Lien;

(b) there has been no loss, destruction, or damage (in each case, whether or not insured) affecting any Acquired Asset;

(c) there has not been any sale, pledge, disposition, transfer, lease, license, encumbrance or authorization of the sale, pledge, disposition, transfer, lease, license or encumbrance of any assets, including any Intellectual Property, that are (or would otherwise be) Acquired Assets, other than sales of Products in the Ordinary Course of Business;

(d) there has not been any acquisition of any properties, assets or Intellectual Property that constitute Acquired Assets, other than Acquired Assets that would not reasonably be expected to result in any Assumed Liabilities;

(e) there has not been any settlement by Prophylix of any Action or waiver of any Claims or rights of value in a manner that constitutes an Assumed Liability or otherwise would reasonably be expected to be materially adverse to the Acquired Assets or the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products;

(f) Prophylix has not terminated, cancelled, allowed to lapse, adversely amended, waived or adversely modified any Governmental Authorizations material to the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products or the Acquired Assets;

(g) Prophylix has not waived a provision of, or amended or modified any Assumed Contract;

(h) there has not been any abandonment, termination or lapse of any Intellectual Property, or rights relating to any Products Intellectual Property;

(i) there has not been any transfer, assignment or grant of any license or sublicense of any rights under or with respect to any Products Intellectual Property;

(j) no event or circumstance has occurred that has had, or would reasonably be expected to have, a Material Adverse Effect; and

(k) Prophylix has not entered into any Contractual Obligation to do any of the things referred to elsewhere in this Section.

4.7. Debt. Neither the execution, delivery or performance of this Agreement or any Transfer Agreement, nor the consummation of the Contemplated Transactions shall give rise, with or without the passage of time, to any default, violation, termination event, call right, put right, acceleration of any payment, repurchase option or other Liability or Lien under any item of Debt.

4.8. Acquired Assets. Prophylix has sole and exclusive, good and marketable title to all of the Acquired Assets, including the Intellectual Property described in the IPR Assignment Agreement, and such title shall be fully transferred, conveyed and assigned to Rallybio at the Closing. None of the Acquired Assets is subject to any Lien, either before or immediately after giving effect to the Contemplated Transactions.

4.9. Intellectual Property.

4.9.1. Intellectual Property Schedules.

(a) Schedule 4.9.1(a).

Part 1 of Schedule 4.9.1(a) lists all of the Patents, registered Copyrights and all registered Trademarks (and Trademarks, including domain names, for which applications for registration have been filed) that are included in the Acquired Intellectual Property and owned by Prophylix as of the Execution Date, setting forth in each case the jurisdictions in which patents have been issued, patent applications have been filed, trademarks have been registered and trademark applications have been filed.

Part 2 of Schedule 4.9.1(a) lists all of the Patents, registered Copyrights and all registered Trademarks (and Trademarks, including domain names, for which applications for registration have been filed) that are included in the Acquired Intellectual Property and licensed to Prophylix or in which Prophylix has any right, title or interest as of the date of this Agreement, other than those owned solely by Prophylix.

To Prophylix's Knowledge, none of the issued Patents, registered Trademarks and registered Copyrights included in the Acquired Intellectual Property and existing as of the Execution Date are invalid or unenforceable. There have been no misrepresentations or concealment of any material information to the U.S. Patent and Trademark Office or other applicable Governmental Authority, or in connection with the prosecution of such Patents, in violation of 37 C.F.R. Section 1.56 or similar disclosure requirements. Except as set forth on Schedule 4.9.1(a), Prophylix has not granted any right, title or interest to any Third Party to the Acquired Intellectual Property listed in Schedule 4.9.1(a) that remains in effect on the Execution Date.

(b) Prophylix does not own or control any Intellectual Property that (i) will not either be assigned or licensed to Rallybio at the Closing and (ii) may be necessary or useful to research, develop, manufacture, make, use, sell, offer for sale, import, export or otherwise exploit the Products, as is currently being conducted.

(c) No current or former Representative of Prophylix has any right, title or interest in, to or under any Acquired Intellectual Property that has not been fully assigned to Prophylix. As of the Execution Date, no Third Party has challenged, or to Prophylix's Knowledge, is challenging or is threatening to challenge the right, title or interest of Prophylix in, to or under Acquired Intellectual Property, or the validity, enforceability, claim construction (with respect to issued Patents), or the scope of proposed claims (with respect to applications for Patents), of any Patents included in the Acquired Intellectual Property.

(d) Schedule 4.9.1(d) lists all oral and written contracts, agreements, and licenses under which Prophylix has any right, title or interest in, under or to any Patents within the Products Intellectual Property (collectively, the "**Inbound License Agreements**"), indicating for each the title, the parties thereto and the effective date thereof. Complete un-redacted and accurate copies of the Inbound License Agreements have been made available by Prophylix to Rallybio. All Inbound License Agreements are in full force and effect and have not been modified or amended. Neither Prophylix (nor, to Prophylix's Knowledge, the Third Party licensor in an Inbound License Agreements) is in default with respect to a material obligation under such Inbound License Agreements, and neither such party has claimed or, to Prophylix's Knowledge, has grounds upon which to claim that the other party is in default with respect to a material obligation under, any Inbound License Agreements.

(e) No Person has asserted, or to Prophylix's Knowledge, is asserting or is threatening to assert a Claim against Prophylix that would adversely affect the ownership rights of Prophylix in, under or to (i) any Products Intellectual Property or (ii) any Inbound License Agreements.

(f) Prophylix has put in place policies and procedures according to reasonable industry standards, as are customary for similarly situated companies in the biopharmaceutical and biotechnology industry with respect to products at a similar stage of development or commercialization, to protect and maintain the confidentiality of any trade secrets, proprietary know-how, and other proprietary, non-public information included in the Products Intellectual Property. There are no outstanding obligations to pay any amounts or provide other consideration to any other Person in connection with any Products Intellectual Property.

(g) To Prophylix's Knowledge, the research, making, manufacture, development, use, sale, offering for sale, importing, and commercialization of Products in the United States as manufactured by Prophylix on the Execution Date does not infringe, or constitute contributory infringement, inducement to infringe, or misappropriation of Intellectual Property of any other Person. Prophylix has not received any written notice or other communication asserting the research, making, manufacture, development, use, sale, offering for sale, importing, or commercialization of Products in any country as manufactured on the Execution Date infringes, or constitutes contributory infringement, inducement to infringe, or misappropriation of Intellectual Property of any other Person that remains unresolved.

(h) To Prophylix's Knowledge, no Intellectual Property listed on Schedule 4.9.1(a) is being infringed or misappropriated by any Third Party.

(i) Prophylix does not own any software that is used with respect to the Products, other than software generally available to the public.

(j) To Prophylix's Knowledge, no action has been taken, or has failed to be taken, in each case by Prophylix that reasonably would be expected to result in the abandonment, cancellation, forfeiture, relinquishment, invalidation or unenforceability of any Products Intellectual Property (including failure to pay required fees associated with registrations or maintenance of such Products Intellectual Property; failure to disclose any known prior art in connection with the prosecution of patent applications with respect to the Patents within the Products Intellectual Property; or failure to make timely post- registration filing of affidavits of use and incontestability and renewal applications in the case of registered Trademarks).

4.9.2. No Infringement or Violation by Prophylix; No Loss of Rights.

(a) To Prophylix's Knowledge, none of the activities of Prophylix or its Representatives in connection with the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products violates any agreement or arrangement which any such Representative has with a current or former employer. All Representatives who contributed to the discovery or development of any Products Intellectual Property did so either (a) within the scope of their employment such that, in accordance with applicable Legal Requirements, all Products Intellectual Property arising therefrom became the exclusive property of Prophylix or is validly licensed to Prophylix or (b) pursuant to written agreements assigning all Products Intellectual Property arising therefrom to Prophylix (or the owner thereof with respect to Intellectual Property licensed to Prophylix) and such assignment documents have to the extent necessary been duly filed in all relevant patent offices.

(b) In connection with the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products, Prophylix has not engaged in unfair competition or trade practices. Prophylix has not received any written or oral notice or claim asserting that unfair competition or trade practices is occurring or has occurred in connection with the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products.

(c) To Prophylix's Knowledge, no loss or expiration of any Intellectual Property licensed to Prophylix under any Inbound License Agreement is pending, reasonably foreseeable or threatened, except for the expiration of certain Patents at the end of their statutory term. To Prophylix's Knowledge, the rights licensed under each Inbound License Agreement will be exercisable by Rallybio to the same extent as by Prophylix prior to the Acquisition, subject to necessary consents from the applicable licensor(s). To Prophylix's Knowledge, no licensor under any Inbound License Agreement has any exclusive license rights in or with respect to any improvements made by Prophylix to the licensed Products Intellectual Property.

(d) To Prophylix's Knowledge, neither this Agreement nor the consummation of the Contemplated Transactions will result in Rallybio being bound by, or subject to, any non-compete or other restriction on the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products.

4.10. Legal Compliance; Permits.

4.10.1. General Compliance.

(a) Prophylix is not in breach or violation of, or default under, and has not been in breach or violation of, or default under (i) any of Prophylix's Organizational Documents or (ii) in any material respect, any Legal Requirement applicable to the Acquired Assets, the Products or the Assumed Liabilities.

(b) All Permits required for Prophylix to conduct its business as currently conducted or for the ownership and use of the Acquired Assets or the Products have been obtained by Prophylix and are valid and in full force and effect. All fees and charges with respect to such Permits as of the date hereof have been paid in full. Schedule 4.10.1(b) lists all current Permits issued to Prophylix which are related to the conduct of its business as currently conducted or the ownership and use of the Acquired Assets or the Products including the names of the Permits and their respective dates of issuance and expiration. To Prophylix's Knowledge, no event has occurred that, with or without notice or lapse of time or both, would reasonably be expected to result in the revocation, suspension, lapse or limitation of any Permit set forth in Schedule 4.10.1(b).

4.10.2. Health Authority Compliance.

(a) The Products subject to the jurisdiction of the United States Food and Drug Administration, or any successor agency thereto ("**FDA**") under the Federal Food, Drug and Cosmetic Act ("**FDCA**"), the EMA or similar Government Authority or Legal Requirements in any jurisdiction, that is, as of the Execution Date, manufactured, tested, developed, distributed, held, sold or marketed by or on behalf of Prophylix is being manufactured, researched, tested, developed, distributed, held, sold and marketed by or on behalf of Prophylix in compliance with all applicable United States and European Union Legal Requirements.

(b) Prophylix has provided to Rallybio copies of all documents in the possession (including electronic access permitting downloads via a data room) of Prophylix material to assessing compliance with the FDCA and its implementing regulations (and similar foreign Legal Requirements in the European Union and other jurisdictions) with respect to the Products, including copies of (i) all warning letters and untitled letters, notices of adverse findings and similar correspondence, and (ii) any document concerning any significant oral or written communication received from the FDA, the EMA, or similar Government Authorities in any jurisdiction. Prophylix has provided to Rallybio all material FDA and EMA correspondence and official minutes from meetings with respect to the Products, whether in person, by telephone, or otherwise, in each case that are in the possession of Prophylix (including electronic access permitting downloads via a data room).

(c) Prophylix has not received any notice that the FDA or EMA has initiated, or threatened to initiate, any action to suspend the research, study, use, marketing or sale of the Products.

(d) With respect to the Products, Prophylix: (i) has not made an untrue statement of a material fact or a fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would provide a basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities policy set forth in the FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09), or (ii) has not been convicted of any crime or engaged in any conduct that would result in debarment under 21 U.S.C. 335a or any similar Legal Requirement.

(e) Prophylix has not received any written notice or communications from any Governmental Authority alleging any material safety or quality concerns with respect to any Products or noncompliance with any applicable Legal Requirements or Governmental Authorizations.

(f) All clinical trials and post-marketing studies for the Products that have been or are being conducted by or on behalf of Prophylix were conducted, and are being conducted, in all material respects in accordance with all applicable Legal Requirements. There is no past, or, to Prophylix's Knowledge, pending or threatened Action by any Governmental Authority to suspend, investigate or terminate any clinical trials or studies for the Products.

(g) Prophylix has not received any (i) written notice from the FDA or any other Governmental Authority alleging any violation of the FDCA, the PHSA, the United States anti-kickback statute, The False Claims Act (31 U.S.C. § 3729–3733) or false claims acts under state Legal Requirements, commencing or indicating an intention to conduct an investigation, audit, or review; or (ii) other written documents issued by the FDA or any other Governmental Authority alleging lack of compliance with any Legal Requirement by Prophylix, any of its Affiliates, or Persons who are otherwise performing services for the benefit of Prophylix or its Affiliates.

4.10.3. Compliance Systems. With respect to the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products, to the extent applicable to Prophylix and the Products, Prophylix has complied and continue to comply, in all material respects, with, and maintains systems and programs to ensure compliance, in all material respects, with, applicable requirements of the FDCA, the Prescription Drug Marketing Act (the "**PDMA**") and the rules and regulations issued under the FDCA, the PDMA, and similar or related foreign Legal Requirements pertaining to programs or systems regarding product quality, notification of facilities and products, corporate integrity, pharmacovigilance and conflict of interest including requirements applicable to the debarment of individuals, requirements applicable to the conflict of interest of clinical investigators and Adverse Drug Reaction Reporting requirements.

4.10.4 Data Protection Compliance. There are no complaints, reports or allegations against Prophylix with respect to (a) the unauthorized or improper use, disclosure or processing of personal data, personal information, or protected health information, or similarly defined term for individually identifiable information ("**Personal Data**") concerning the researching, developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products (including plasma supply) or (b) any actual or suspected violations by Prophylix of the General Data Protection Regulation ("**GDPR**"), the Health Insurance Portability and Accountability Act of 1996 and its associated regulations ("**HIPAA**"), or other data protection Legal Requirement whether by a Governmental Authority, a patient, a plan member, a current or former employee or volunteer or any other Person. Prophylix is in compliance with the GDPR, both in its capacity as a data controller and a data processor, as applicable. Prophylix is in compliance with all Legal Requirements relating to the use, disclosure, and processing of Personal Data, including the use in connection with the collection and transfer of plasma, except where the failure to comply with a Legal Requirement would not have a Material Adverse Effect individually or in the aggregate.

4.10.5 Permits. To Prophylix's Knowledge, there are no Governmental Authorizations owned by Prophylix that relate in part to the Products but do not solely relate to the Products that Rallybio cannot otherwise obtain on its own, except for the Governmental Authorizations for the Products that would be necessary to research, develop, manufacture, make, use, sell, offer for sale, import, export or otherwise exploit the Products.

4.11. Contracts.

4.11.1. Specified Contracts. Section 4.11 of the Disclosure Schedule sets forth, as of the Execution Date, to the extent Prophylix is a party to a Contractual Obligation:

(a) any licenses of Products Intellectual Property;

(b) any manufacturing or supply agreement with respect to the Products or any component thereof;

(c) any Contractual Obligation consisting of a partnership, limited liability company or joint venture agreement;

(d) any Contractual Obligation with any Governmental Authority;

(e) any Contractual Obligations between Prophylix and its Affiliates; and

(f) any such Contractual Obligations that are material to the Products or the Acquired Assets.

4.11.2. Contracts. Prophylix has delivered or made available to Rallybio true, accurate and complete copies of each written Contractual Obligation listed on Schedule 4.9.1(d) or Schedule 2.1(e), in each case, as amended or otherwise modified and in effect.

4.11.3. Enforceability, etc. To Prophylix's Knowledge, each Assumed Contract is Enforceable against each party to such Contractual Obligation, and is in full force and effect, and, subject to obtaining any necessary consents, will continue to be so Enforceable and in full force and effect on identical terms following the consummation of the Contemplated Transactions in favor of Rallybio.

4.11.4. Breach, etc. Neither Prophylix, nor, to Prophylix's Knowledge, any other party to any Assumed Contract is in breach or violation of, or default under, or has repudiated any provision of, any Assumed Contract in any material respect.

4.12. Litigation and Governmental Orders. With respect to the Products, there is no Action to which Prophylix is a party (either as plaintiff or defendant) or, to Prophylix's Knowledge, to which any Acquired Assets are subject pending or threatened, nor is there any reasonable basis for any of the foregoing. As of the Execution Date, there is no Action which Prophylix presently intends to initiate. No Governmental Order has been received which is applicable to, or otherwise has or would reasonably be expected to have a Material Adverse Effect.

4.13. Insurance. Section 4.13 of the Disclosure Schedule sets forth (a) a true and complete list of all current policies or binders of fire, liability, product liability, umbrella liability, vehicular, fiduciary liability and other casualty and property insurance maintained by Prophylix and relating to the Assumed Assets or the Assumed Liabilities (collectively, the "**Insurance Policies**"); and (b) with respect to the Assumed Assets or the Assumed Liabilities, a list of all pending claims and the claims history for Prophylix since January 1, 2016. There are

no claims related to the Assumed Assets or the Assumed Liabilities pending under any such Insurance Policies as to which coverage has been questioned, denied or disputed or in respect of which there is an outstanding reservation of rights. Prophylix has not received any written notice of cancellation of, premium increase with respect to, or alteration of coverage under, any of such Insurance Policies. All premiums due on such Insurance Policies have either been paid or, if not yet due, accrued. All such Insurance Policies (x) are in full force and effect and, to Prophylix's Knowledge, enforceable in accordance with their terms; (y) are provided by carriers who are financially solvent; and (z) have not been subject to any lapse in coverage. Prophylix is not in default under, or has otherwise failed to comply with, in any material respect, any provision contained in any such Insurance Policy. The Insurance Policies are sufficient for compliance with all applicable Legal Requirements and Contractual Obligations to which Prophylix is a party or by which it is bound.

4.14. Powers of Attorney. Prophylix has no general or special powers of attorney outstanding (whether as grantor or grantee thereof) with respect to the Acquired Assets or the Assumed Liabilities.

4.15. No Brokers. Prophylix has no Liability of any kind to, and is not subject to any claim of, any broker, finder or agent in connection with the Contemplated Transactions for which Rallybio could be liable.

4.16. Certain Business Practices. With respect to the Products, neither Prophylix nor, to Prophylix's Knowledge, any Representative of Prophylix has directly or indirectly (a) used any funds of Prophylix for unlawful contributions, gifts, entertainment or other unlawful expenses; (b) made, promised or authorized the making of any unlawful payment or the unlawful provision of anything of value to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns or violated any provision of the Foreign Corrupt Practices Act of 1977; (c) made any payment with Prophylix funds or improperly provided anything of value in the nature of bribery; or (d) established or maintained any unrecorded fund or asset or made any false entries on any books or records for any purpose.

4.17. Taxes. Prophylix has timely filed all Tax Returns required to be filed by Prophylix in connection with the ownership and operation of the Acquired Assets. Prophylix has paid all Tax Liabilities owed by it in connection with the ownership and operation of the Acquired Assets, whether or not shown on such Tax documents and there are no Tax Liens on the Acquired Assets.

4.18. Undisclosed Liabilities. Prophylix has no Liabilities with respect to the Acquired Assets or the Products, except (a) those which are adequately reflected or reserved against in the Financial Statements, (b) those which have been incurred in the Ordinary Course of Business consistent with past practice since December 31, 2018 and that are not, individually or in the aggregate, material in amount, and (c) those which are identified on Section 4.18 of the Disclosure Schedule.

4.19. Solvency; Fraudulent Conveyance. As of the Closing Date, after giving effect to all of the Contemplated Transactions, including the payment of the Purchase Price, Prophylix shall be Solvent. For the purposes of this Section 4.19, the term "**Solvent**" when used with respect to any Person, means that, as of any date of determination, the "fair saleable value" of the assets of such Person will, as of such date, exceed (a) the value of all "liabilities of such Person, including contingent and other liabilities," as of such date, as such quoted terms are generally determined in accordance with applicable federal laws governing determinations of the insolvency of debtors, and (b) the amount that will be required to pay the probable liabilities of such Person on its existing Debts (including contingent liabilities) as such Debts become absolute and matured. Prophylix does not contemplate the commencement of insolvency, bankruptcy, liquidation or consolidation proceedings or the appointment of a receiver, liquidator, conservator, trustee or similar official in respect of Prophylix or any of its assets. The amount of consideration being received by Prophylix upon the sale of the Acquired Assets to Rallybio constitutes fair market value and fair consideration for the right, title and interest in, to and under the Acquired Assets. Prophylix is not transferring the Acquired Assets and the Assumed Liabilities to Rallybio with any intent to hinder, delay or defraud any of the Prophylix's creditors.

4.20 Full Disclosure. The representations and warranties contained in this Section 4 are complete and correct as of the date hereof, and will be complete and correct as of the Closing Date. No representation or warranty of Prophylix contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements contained herein or therein not misleading.

5. REPRESENTATIONS AND WARRANTIES OF RALLYBIO.

Rallybio represents and warrants to Prophylix that the statements contained in this Section 5 are true and correct:

5.1. Organization. Rallybio is (a) duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and (b) duly qualified to do business and in good standing in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification necessary, other than in such jurisdiction where the failure to be so qualified individually or in the aggregate has not had and would not reasonably be expected to have a material adverse effect on Rallybio.

5.2. Power and Authorization. The execution, delivery and performance by Rallybio of this Agreement, and the consummation by Rallybio of the Contemplated Transactions are within the corporate power and authority of Rallybio, and have been duly authorized by all necessary action on the part of Rallybio. This Agreement has been duly executed and delivered by Rallybio and, assuming the due authorization, execution and delivery by Prophylix, is a legal, valid and binding obligation of Rallybio, Enforceable against Rallybio in accordance with its terms subject to the effects of bankruptcy, insolvency or other Legal Requirements of general application affecting the enforcement of creditor rights.

5.3. Authorization of Governmental Authorities. No action by (including any authorization, consent or approval), or in respect of, or filing with, any Governmental Authority is required for, or in connection with, the valid and lawful (a) authorization, execution, delivery and performance by Rallybio of this Agreement and the Transfer Agreements or (b) the consummation of the Contemplated Transactions by Rallybio.

5.4. Non-contravention. Neither the execution, delivery and performance by Rallybio of this Agreement or the Transfer Agreements nor the consummation of the Contemplated Transactions will:

(a) violate any Legal Requirement applicable to Rallybio;

(b) result in a breach or violation of, or default under, any Contractual Obligation of Rallybio;

(c) require any action by (including any authorization, consent or approval) or in respect of (including notice to), any Person under any Contractual Obligation of Rallybio; or

(d) result in a breach or violation of, or default under, Rallybio's Organizational Documents.

5.5. Financing. Rallybio will have (i) on the Closing Date all funds necessary to pay the Closing Payment and (ii) otherwise all funds necessary to pay its other obligations under this Agreement when due.

5.6. No Brokers. Rallybio does not have any Liability of any kind to, nor is Rallybio subject to any claim of, any broker, finder or agent in connection with the Contemplated Transactions for which Prophylix could be liable.

5.7. Disclaimer. Rallybio has undertaken its own investigation and has been provided with and has evaluated such information as requested by Rallybio in connection with such investigation, in connection with the execution, delivery and performance of this Agreement and the documents related thereto to which it is a party and the consummation of the Contemplated Transaction. In making its decision to execute and deliver this Agreement and the documents related thereto and to consummate the Contemplated Transactions, Rallybio is relying solely upon the representations and warranties of Prophylix set forth in Section 4 and in the related transaction documents, and acknowledges that such representations and warranties are the only representations and warranties made by Prophylix and its employees, officers, directors or representatives with respect to this Agreement, the other transaction documents and the Contemplated Transactions, including the Acquired Assets. Except as expressly set forth in Section 4 and in the transaction documents, Rallybio acknowledges and agrees that neither Prophylix nor any other Person is making or has made any representation or warranty, express or implied, as to this Agreement, the other transaction documents and the Contemplated Transactions, including the Acquired Assets.

6. COVENANTS.

6.1. Closing. Prophylix will use its commercially reasonable efforts to take all of the actions and deliver all the various certificates, documents and instruments described in Section 7 as being performed or delivered by Prophylix. Rallybio will use its commercially reasonable efforts to take all of the actions and deliver all the various certificates, documents and instruments described in Section 8 as being performed or delivered by Rallybio.

6.2. Pre-Closing Handling of the Acquired Assets. From the Execution Date to the Closing Date, except as otherwise contemplated by this Agreement or consented to by Rallybio in writing, Prophylix agrees that it will pay or perform all material obligations relating to the Acquired Assets as they become due and owing in the Ordinary Course of Business.

(a) From the Execution Date to the Closing, except as otherwise permitted by this Agreement or consented to by Rallybio in writing, Prophylix shall:

(i) maintain in effect all Products Intellectual Property and applications and registrations included in the Products Intellectual Property, to the extent owned or controlled by Prophylix or its Affiliates;

(ii) maintain in effect and perform its obligations in all material respects under the Assumed Contracts;

(iii) preserve and maintain all Permits required for Prophylix to conduct its business as currently conducted or the ownership and use of the Acquired Assets;

(iv) pay Debts, Taxes and other obligations relating to the Acquired Assets when due;

(v) maintain Acquired Assets in all material respect in the same condition as they were on the date of this Agreement;

(vi) continue in full force and effect without modification all Insurance Policies of Prophylix relating to the Acquired Assets or the Products, except as required by applicable Legal Requirement;

(vii) defend and protect the Acquired Assets and the Products from infringement or usurpation;

(viii) maintain all of its books and records in accordance with IFRS and past practice;

(ix) comply in all material respects with all Legal Requirements applicable to the conduct of Prophylix's business or the ownership and use of the Acquired Assets; and

(x) not agree, commit to, authorize or take or permit any action that would cause (A) any of the foregoing actions, changes, events or conditions described in this Section 6.2(a) to occur or (B) any of the changes, events or conditions in Section 4.5 to be inaccurate or untrue.

(b) From and after the Execution Date and to the Closing, except as Rallybio shall otherwise consent in writing (which consent shall not be unreasonably withheld, conditioned or delayed), Prophylix covenants and agrees that, with respect to the Acquired Assets, it shall not:

(i) sell, pledge, dispose of, transfer, lease, license, encumber or authorize the sale, pledge, disposition, transfer, lease, license or encumbrance of any assets, including the Products Intellectual Property, that are (or would otherwise be) Acquired Assets;

(ii) waive any Claims or rights of material value that relate to the Acquired Assets;

(iii) acquire any material properties, assets or Intellectual Property that would constitute Acquired Assets, other than (A) in the Ordinary Course of Business and (B) Acquired Assets that would not reasonably be expected to result in the assumption by Rallybio of Assumed Liabilities at the Closing pursuant to the terms of this Agreement;

(iv) settle any Action or waive any Claims or rights of material value in a manner that would constitute an Assumed Liability;

(v) terminate, cancel, permit to lapse or be terminated, amend, waive or modify any Governmental Authorizations, except as required by any Governmental Authority;

(vi) enter into any new Contractual Obligation that would be an Assumed Contract or renew any Assumed Contract, other than renewals of (A) any Contractual Obligation that is cancelable upon sixty (60) days or less notice without any liability and

(B) any Contractual Obligation that is necessary or useful to research, develop, manufacture, make, use, sell, offer for sale, import, export or otherwise exploit the Products in the Ordinary Course of Business;

(vii) terminate or waive any material provision of, or amend or otherwise modify in any material respect, any Assumed Contract other than in the Ordinary Course of Business;

(viii) abandon, dispose of or permit to lapse any Intellectual Property contained in the Acquired Assets;

(ix) fail to take any commercially reasonably action to protect or maintain the Products Intellectual Property or to prosecute any pending applications for Products Intellectual Property or file any documents or other information or pay any maintenance or other fees related thereto;

(x) transfer, assign or grant any license or sublicense of any rights under or with respect to any Products Intellectual Property;

(xii) disclose or agree to disclose to any Person, other than Representatives of Rallybio, Third Parties bound by confidentiality agreements in the Ordinary Course of Business or to the extent required to be disclosed to a Governmental Authority, any confidential information solely relating to the Products; or

(xiii) agree, commit to, authorize or take or permit any action that would cause any of the foregoing actions, changes, events or conditions described in this Section 6.2(b) to occur.

6.3. Access to Books and Records. From and for a period of three (3) years after the Closing Date, each Party (the "**Accessed Party**") shall afford to the other Party (the "**Accessing Party**") and to each of its Representatives, no more than once in any 12-month period, reasonable access and duplicating rights at the Accessed Party's corporate offices, during normal business hours and upon reasonable advance written notice (at least 21 days in advance of the proposed visit date), to all books and records (including reasonable access to a knowledgeable employee or other Representative of the Accessed Party to discuss such information) within the possession of the Accessed Party or any of its Affiliates, to the extent relating to the Acquired Assets or the Assumed Liabilities (other than with respect to any Claims between the Parties, whether pursuant to this Agreement or otherwise). Without limiting the foregoing, information may be requested under this Section 6.3 for audit, accounting, Third Party claims, Third Party litigation, and Tax purposes, as well as for purposes of fulfilling disclosure and reporting obligations, and any notice delivered by the Accessing Party under this Section 6.3 will be accompanied by a written list reasonably detailing the purpose, scope and items of information sought to be accessed and duplicated by the Accessing Party during such visit to the Accessed Party's offices.

6.4. No Negotiation by Prophylix. Between the Execution Date and the Closing Date, Prophylix shall not directly or indirectly solicit, initiate, knowingly encourage or entertain any inquiries or proposals relating to the acquisition, exclusive licensing or encumbering in whole or in part of the Acquired Assets or the Products (an "**Acquisition Proposal"**), discuss or negotiate with, provide any information to, consider the merits of any Acquisition Proposal from any Person (other than Rallybio), or consummate any transaction relating to any Acquisition Proposal, or that would otherwise reasonably be expected to compromise Prophylix's ability to consummate the Contemplated Transactions.

6.5. Expenses. With respect to the costs and expenses (including legal, accounting, consulting, advisory and brokerage) incurred in connection with the Contemplated Transactions (the "**Transaction Expenses**"), Rallybio will not have any Liability in respect of the Transaction Expenses of Prophylix, nor will Prophylix have any Liability in respect of the Transaction Expenses of Rallybio.

6.6. Confidentiality. The Mutual Confidential Disclosure Agreement between Rallybio and Prophylix, dated December 6, 2018 (the "**Confidential Disclosure Agreement**") shall be superseded by this Section 6.6 and shall be null and void and of no further force and effect on and after the Closing. Prophylix acknowledges that the success of Rallybio after the Closing depends upon the continued preservation of the confidentiality of certain information possessed by Prophylix, that the preservation of the confidentiality of such information by Prophylix is an essential premise of the bargain between Prophylix and Rallybio, and that Rallybio would be unwilling to enter into this Agreement in the absence of this Section 6.6. Accordingly, Prophylix hereby agrees with Rallybio that Prophylix and its Representatives will not, and that Prophylix will cause its Affiliates not to, at any time on or after the Closing Date, directly or indirectly, without the prior written consent of Rallybio, disclose or use, any confidential or proprietary information within the Acquired Assets or of Rallybio, including any business information, Patents, other Intellectual Property, records, data, formulae, processes, developments, designs, inventions, models, techniques, improvements or discoveries, patentable or otherwise.

6.7. Publicity. No public announcement or disclosure may be made by any Party with respect to the subject matter of this Agreement or the Contemplated Transactions without the prior written consent of Rallybio and Prophylix; *provided, however,* that the provisions of Section 6.6 and this Section 6.7 will not prohibit (a) any disclosure required by any applicable Legal Requirement, including any Legal Requirement or listing standard of any exchange or quotation system on which the disclosing Party's securities are listed or traded (in which case the disclosing Party will provide the other Party with the opportunity to review in advance the disclosure and to contest the same, including reasonable opportunity to seek a protective order or to seek confidential treatment of such disclosures), (b) any disclosure made in connection with the enforcement of any right or remedy relating to this Agreement or the Contemplated Transactions, (c) any disclosure made pursuant to a press release in a form mutually agreed to by Rallybio and Prophylix (or any other subsequent disclosure containing substantially similar information), or (d) any disclosure to any potential acquirer, payment factoring partner, underwriter, licensee, sublicensee, joint venturer, collaborator, bank or financing source of either Party.

6.8. Transfer of Governmental Authorizations On the Closing Date, each Party shall execute and deliver, or cause to be executed and delivered, to the FDA, the EMA and to other appropriate Governmental Authorities, as the case may be, such documents and instruments of conveyance as necessary and sufficient (or as Rallybio may otherwise reasonably request) to effectuate the transfer of each Transferred Governmental Authorization to Rallybio under applicable Legal Requirements on the Closing Date or as soon as possible if the Transferred Governmental Authorizations are assigned after the Closing.

6.9. Further Assurances. From and after the Closing Date, upon the request of either Prophylix or Rallybio, each of the Parties hereto will do, execute, acknowledge and deliver all such further acts, assurances, deeds, assignments, transfers, conveyances and other instruments and papers as may be reasonably required or appropriate to carry out the Contemplated Transactions.

6.10. Scientific Advisory Board. From the Closing Date until Rallybio's payment of Milestone 2 or 3 pursuant to Section 3.3.1 (whichever comes first), the Board of Directors of Prophylix will be entitled to appoint one representative reasonably acceptable to Rallybio to serve on the Scientific Advisory Board of Rallybio. All information concerning the development, manufacturing and commercialization activities for Products that Rallybio elects to share with its Scientific Advisory Board shall be shared equally with all members of the Scientific Advisory Board.

6.11. Diligence.

6.11.1. Products containing NAITgam. Rallybio shall use Commercially Reasonable Efforts to develop and commercialize Products containing NAITgam in the United States and in at least one Major European Market. Such efforts include Rallybio's good faith verification of an adequate supply of plasma to manufacture NAITgam to treat patients both prenatally and postnatally in the United States and in such Major European Market as outlined on Schedule 6.11.1.

6.11.2. Products containing T1 Antibodies. If Rallybio determines, in its reasonable discretion pursuant to Schedule 6.11.1, that the supply of plasma is insufficient to commercialize Products containing NAITgam following Rallybio's continued and diligent efforts to obtain sufficient plasma, Rallybio shall notify Prophylix of such decision in writing not later than ten (10) business days after such determination. From the date of such notification, if any, Rallybio shall use Commercially Reasonable Efforts to develop and commercialize Products containing T1 Antibody in the United States and in at least one Major European Market. Upon such notification, if any, all diligence obligations of Rallybio set forth in Section 6.11.1 shall be deemed satisfied and cease. In the absence of such notification under this Section 6.11.2, Rallybio shall have no diligence obligations with respect to the development or commercialization of any Products containing T1 Antibody.

6.11.3. Status Updates. In January each year, Rallybio shall provide written status updates to Prophylix of Rallybio's development and commercialization activities for Products with details sufficient to describe the activities and efforts undertaken to comply with its obligations under Sections 6.11.1 and 6.11.2, to the extent applicable.

6.12. Repurchase Option. Upon written notice to Rallybio, Prophylix shall have a right (but not an obligation) to repurchase the remaining Acquired Assets (including all CMC and clinical data, documentation, results and approvals) for an amount equal to the Closing Payment if the following events should occur:

(a) If Rallybio, after using Commercially Reasonable Efforts as set out in Section 6.11, elects not to pursue any further development and/or commercialization activities for the Products; or

(b) If Rallybio elects to transfer all or substantially all of the remaining Acquired Assets to a Third Party without including the surviving rights and obligations in Section 6.11, if applicable.

6.13. Technology Transfer and Support. Prophylix shall initiate the transfer to Rallybio (or a Third Party designated by Rallybio) of all Know-How and materials relating to the development and manufacture of the Products, including existing plasma banks and cell banks used for the production of the Products. Technology transfer and additional support to be provided by Prophylix shall be implemented pursuant to a plan based on the activities set forth on Schedule 6.13. All technology transfer activities set forth on Schedule 6.13 shall be completed within the time periods set forth in such Schedule.

6.14. Additional Support. For a period of three (3) years following the Closing, Rallybio and its subsidiaries, on the one hand, and Prophylix, on the other hand, shall reasonably cooperate with each other in the defense or settlement of any Liabilities or lawsuits involving the Acquired Assets, the Products, the Agreement or the Transfer Agreements (other than with respect to any Claims between the Parties, whether pursuant to this Agreement or otherwise), in each case for which the other Party has responsibility under this Agreement, by providing the other Party and such other Party's legal counsel reasonable access to employees, records, documents, data, equipment, facilities, products, and other information relating primarily to the

Acquired Assets or the Products, as such other Party may reasonably request, to the extent maintained or under the possession or control of the requested Party; *provided, however,* that such access shall not unreasonably interfere with the business of Rallybio or Prophylix, or any of their respective Affiliates; *provided, further,* that either Party may restrict the foregoing access to the extent that (a) such restriction is required by applicable Legal Requirements, or (b) disclosure of any such information would result in the loss or waiver of the attorney-client privilege. The requesting Party shall reimburse the other Party for reasonable out-of-pocket expenses paid by the other Party to Third Parties in performing its obligations under this Section 6.14.

7. CONDITIONS TO RALLYBIO'S OBLIGATIONS AT THE CLOSING.

The obligation of Rallybio to consummate the Closing is subject to the fulfillment of each of the following conditions (unless waived by Rallybio in accordance with Section 12.3):

7.1. Representations and Warranties. The representations and warranties of Prophylix set forth in this Agreement (a) that are not qualified by materiality or Material Adverse Effect, will be true and correct in all material respects at and as of the Closing with the same force and effect as if made as of the Closing and (b) that are qualified by materiality or Material Adverse Effect, will be true and correct in all respects at and as of the Closing with the same force and effect as if made as of the Closing, in each case, other than representations and warranties that expressly speak only as of a specific date or time, which will be true and correct as of such specified date or time.

7.2. Performance. Prophylix will have performed and complied in all material respects, with all agreements, obligations and covenants contained in this Agreement and the Transfer Agreements that are required to be performed or complied with by it at or prior to the Closing.

7.3. No Material Adverse Effect. Since the Execution Date, there will have occurred no events nor will there exist circumstances which singly or in the aggregate have resulted in a Material Adverse Effect.

7.4. [Intentionally Omitted].

7.5. Qualifications. No provision of any applicable Legal Requirement and no Governmental Order will prohibit the consummation of any of the Contemplated Transactions.

7.6. Absence of Litigation. No Action will be pending or threatened in writing by a Governmental Authority which may result in a Governmental Order (nor will there be any Governmental Order in effect) (a) which would prevent consummation of any of the Contemplated Transactions or (b) which would result in any of the Contemplated Transactions being rescinded following consummation.

7.7. IPR Assignment Agreement. Prophylix shall have exercised the option to acquire all Intellectual Property pursuant to the terms of the Exclusive License Agreement, dated July 28, 2015, as amended, [***] (the "[***] **License**") and Prophylix and the parties to the [***] License shall have executed and delivered a fully-executed of the IPR Assignment

Agreement to Rallybio in form and substance reasonably acceptable to Rallybio (the "**IPR Assignment Agreement**"). The Parties agree to allocate the Sign-On Fee as follows: (a) Prophylix shall be responsible for $[***]; and (b) Rallybio shall be responsible for the balance of the Sign-On Fee. The Parties further agree that Rallybio shall offset Prophylix's share of the Sign-On Fee against the payment to be made to Prophylix at Closing as provided in Section 3.1, and Rallybio shall pay the entire Sign-On Fee in accordance with Section 4.1(A) of the IPR Assignment Agreement following the assignment to, and assumption by, Rallybio of the IPR Assignment Agreement.

7.8. Consents, etc. All actions by (including any authorization, consent or approval) or in respect of (including notice to), or filings with, any Governmental Authority or other Person that are required to consummate the Contemplated Transactions, as set out in Schedule 7.8, will have been obtained or made, in a manner satisfactory in form and substance to Rallybio, and no such authorization, consent or approval will have been revoked.

7.9. Transfer Agreements. Each Transfer Agreement will have been executed and delivered to Rallybio by Prophylix.

7.10. Permits. Rallybio shall have received all Permits that are necessary for it to conduct the business of Prophylix as conducted by Prophylix as of the Closing Date and for the ownership and use of the Acquired Assets or the Products.

7.11. Liens. All Liens relating to the Acquired Assets shall have been released in full and Prophylix shall have delivered to Rallybio written evidence, in form satisfactory to Rallybio in its sole discretion, of the release of such Liens.

7.12. Other Documents. Prophylix shall have delivered to Rallybio such other documents or instruments as Rallybio reasonably requests and are reasonably necessary to consummate the Contemplated Transactions.

8. CONDITIONS TO PROPHYLIX'S OBLIGATIONS AT THE CLOSING.

The obligation of Prophylix to consummate the Closing is subject to the fulfillment of each of the following conditions (unless waived by Prophylix in accordance with Section 12.3):

8.1. Representations and Warranties. The representations and warranties of Rallybio contained in this Agreement (a) that are not qualified by materiality or material adverse effect will be true and correct in all material respects at and as of the Closing with the same force and effect as if made as of the Closing and (b) that are qualified by materiality or material adverse effect will be true and correct in all respects at and as of the Closing with the same force and effect as if made as of the Closing, in each case, other than representations and warranties that expressly speak only as of a specific date or time, which will be true and correct as of such specified date or time.

8.2. Performance. Rallybio will have performed and complied with, in all material respects, all agreements, obligations and covenants contained in this Agreement that are required to be performed or complied with by Rallybio at or prior to the Closing.

8.3. [Intentionally Omitted]

8.4. Qualifications. No provision of any applicable Legal Requirement and no Governmental Order will prohibit the consummation of any of the Contemplated Transactions.

8.5. Absence of Litigation. No Action will be pending or threatened in writing by a Governmental Authority which may result in a Governmental Order (nor will there be any Governmental Order in effect) (a) which would prevent consummation of any of the Contemplated Transactions or (b) which would result in any of the Contemplated Transactions being rescinded following consummation.

8.6. Transfer Agreements. The Bill of Sale and Assignment and Assumption Agreement will have been executed and delivered to Prophylix by Rallybio.

8.7. Guarantee. Rallybio Holdings, LLC will have executed and delivered to Prophylix the Guarantee.

8.8. Compliance and Regulatory. Rallybio will be prepared to accept transfer of the Transferred Governmental Authorizations (including all obligations under such Transferred Governmental Authorizations) under Section 6.8.

9. TERMINATION.

9.1. Termination of Agreement. This Agreement may be terminated (the date on which the Agreement is terminated, the "**Termination Date**") at any time prior to the Closing:

(a) by mutual written consent of Rallybio and Prophylix;

(b) by Rallybio if either (i) there will be a material breach of, or material inaccuracy in, any representation or warranty of Prophylix contained in this Agreement as of the Execution Date or as of any subsequent date (other than representations or warranties that expressly speak only as of a specific date or time, with respect to which Rallybio's right to terminate will arise only in the event of a breach of, or inaccuracy in, such representation or warranty as of such specified date or time) or (ii) Prophylix will have breached or violated in any material respect any of its covenants and agreements contained in this Agreement, which breach or violation, in the case of either clause (i) or

(ii) above, would give rise, or would reasonably be expected to give rise, to a failure of a condition set forth in Section 7 and cannot be or has not been cured on or before the earlier of five (5) Business Days before the Drop Dead Date or twenty (20) Business Days after Rallybio notifies Prophylix of such breach or violation;

(c) by Prophylix if either (i) there will be a material breach of, or material inaccuracy in, any representation or warranty of Rallybio contained in this Agreement as of the Execution Date or as of any subsequent date (other than representations or warranties that expressly speak only as of a specific date or time, with respect to which Prophylix's right to terminate will arise only in the event of a breach of, or inaccuracy in, such representation or warranty as of such specified date or time) or (ii) Rallybio will have breached or violated in any material respect any of its covenants and agreements

contained in this Agreement, which breach or violation, in the case of either clause (i) or (ii) above, would give rise, or would reasonably be expected to give rise, to a failure of the condition set forth in Section 8 and cannot be or has not been cured on or before the earlier of five (5) Business Days before the Drop Dead Date or twenty (20) Business Days after Prophylix notifies Rallybio of such breach or violation;

(d) by Rallybio if Prophylix has breached its obligations under Section 6.4 and such breach has not been cured within twenty-four (24) hours of notice by Rallybio of such breach;

(e) by either Party by providing notice to each other Party at any time after September 30, 2019 (the "**Drop Dead Date**") if the Closing will not have occurred by reason of the failure of any condition set forth in Section 7 or Section 8 to be satisfied (unless such failure is the result of one or more breaches or violations of, or inaccuracy in any covenant, agreement, representation or warranty of this Agreement by the Party providing such notice, in which case the Drop Dead Date will be extended to December 31, 2019); or

(f) by either Rallybio or Prophylix if a final non-appealable Governmental Order permanently enjoining, restraining or otherwise prohibiting the Closing will have been issued by a Governmental Authority of competent jurisdiction.

9.2. Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1, this Agreement *other than* the provisions of Sections 4.15 (No Brokers), 5.6 (No Brokers), 6.5 (Expenses), 6.6 (Confidentiality), 6.7 (Publicity), 11 (Tax Matters), 12.9 (Governing Law), and this Section 9.2, will then be null and void and have no further force and effect and all other rights and Liabilities of the Parties hereunder will terminate without any Liability of any Party to any other Party, except for Liabilities arising in respect of willful breaches under this Agreement by any Party on or prior to the Termination Date.

10. INDEMNIFICATION; WAIVER.

10.1. Indemnification by Prophylix. Subject to the limitations set forth in this Section 10, Prophylix will indemnify and hold Rallybio and each of its Affiliates and Representatives (each, a "**Rallybio Indemnified Person**") harmless from, against and in respect of any and all losses, damages, assessments, fines, penalties, Taxes, Actions, Liabilities, fees, costs (including reasonable costs of investigation, defense and enforcement of this Agreement), expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts fees and expenses), whether or not involving a Third Party Claim (collectively, "**Losses**"), incurred or suffered by the Rallybio Indemnified Persons or any of them on or after the Closing as a result of:

(a) any common law fraud or intentional misrepresentation of Prophylix or any of Prophylix's officers;

(b) any breach of, or inaccuracy in, any representation or warranty made by Prophylix in this Agreement or in any Transfer Agreement or any instrument or certificate delivered pursuant to this Agreement as if made on both the Execution Date and at the Closing (except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties will be deemed to be made only as of such date)) (in each case, solely for determining any Losses, as such representation or warranty would read if all qualifications as to materiality, including each reference to the defined term "Material Adverse Effect," were deleted therefrom);

(c) any breach or violation of any covenant or agreement of Prophylix (including under this Section 10) in this Agreement or any Transfer Agreement or any instrument or certificate delivered pursuant to this Agreement; or

(d) the Excluded Liabilities.

10.2. Indemnification by Rallybio. Subject to the limitations set forth in this Section 10, Rallybio will indemnify and hold Prophylix and each of its Affiliates and Representatives (each, a "**Prophylix Indemnified Person**") harmless from and against and in respect of any and all Losses incurred or suffered by the Prophylix Indemnified Persons or any of them on or after the Closing as a result of:

(a) any common law fraud or intentional misrepresentation of Rallybio or any of its officers;

(b) any breach of, or inaccuracy in, any representation or warranty made by Rallybio in this Agreement or in any Transfer Agreement or any instrument or certificate delivered pursuant to this Agreement as if made on both the Execution Date and at the Closing (except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties will be deemed to be made only as of such date)) (in each case, solely for determining any Losses, as such representation or warranty would read if all qualifications as to materiality, including each reference to the term "material adverse effect," were deleted therefrom);

(c) any breach or violation of any covenant or agreement of Rallybio (including under this Section 10) in or pursuant to this Agreement or any Transfer Agreement or any instrument or certificate delivered pursuant to this Agreement; or

(d) the Assumed Liabilities.

10.3. Financial Limitations. The liability of Prophylix under Section 10.1(b) is subject to the following limitations:

(a) With respect to Losses arising from or relating to a breach of the representations and warranties in Section 4, except for breach of Fundamental Warranties, Prophylix shall have no indemnification obligation for such Loss unless and until the aggregate amount of all such Losses of all Rallybio Indemnified Persons equals or exceeds [***] of the aggregate amount of the Closing Payment (as set out in Section 3.1) and the milestone payments (as set out in Section 3.3) (such amount, the "**Basket**"), in which event the Indemnifying Party shall then be liable for the full amount of such Losses, including the Losses equal to or less than the Basket, subject to any applicable limitations set forth in Section 10;

(b) Except for breaches of Fundamental Warranties, the aggregate liability of Prophylix to Rallybio and any Rallybio Indemnified Person pursuant to Section 10.1(b) shall not exceed [***] of the aggregate amount of (i) $[***] and (ii) the milestone payments (as set out in Section 3.3).

10.4. Settlement of Claims.

(a) Any indemnification claims relating to Prophylix's breach of representations and warranties in Section 4, except for breach of Fundamental Warranties, shall be settled as follows:

(i) Any Rallybio Indemnified Person may claim a direct payment in the form of up to $[***] of the Closing Payment, subject in all cases to the liability cap set forth in Section 10.3(b); and

(ii) Any Rallybio Indemnified Person may set-off any Loss against the milestone payments set out in Section 3.3 until the claim has been paid in full, subject in all cases to the liability cap set forth in Section 10.3(b).

(b) If at any time Prophylix shall become liable for any Losses under this Section 10, then in addition to any rights of set-off, offset or other rights that Rallybio may expressly have under this Agreement (including, but not limited to, pursuant to Section 10.4(a)) Rallybio may, but is not obligated to, elect to offset all or a portion of such Losses from and against any amounts owed to Prophylix under Section 3. Neither the exercise of nor failure to exercise any such right of set-off shall constitute an election of remedies or limit Rallybio in any manner in the enforcement of other remedies available to it hereunder and the exercise by Rallybio of the right of set-off against any amounts payable to Prophylix pursuant to this Agreement shall not be the sole or exclusive remedy of Rallybio for recovery of any amounts owed by Prophylix to Rallybio pursuant to this Agreement.

10.5. Time Limitations.

10.5.1. Notice of Claim. An Indemnified Party shall, as soon as reasonably practicable after the Indemnified Party has actual knowledge of such Loss, notify in writing the Indemnifying Party, and such written notice shall specify the factual basis of that claim in reasonable detail to the extent then known to the Indemnified Party; provided, however, that any failure by the Indemnified Party to give such notice in a timely manner shall not limit the indemnification obligations of the Indemnifying Party under this Section 10 except to the extent that the Indemnifying Party is actually prejudiced by such failure.

10.5.2. Disputes. If the Indemnifying Party disputes any claim for indemnification brought by the Indemnified Party, then the Indemnifying Party shall have no liability with respect to such claim unless the Indemnified Party initiates dispute resolution proceedings pursuant to Section 12.9 within ninety (90) Business Days after the Indemnifying Party has notified the Indemnified Party of such dispute.

10.5.3. Survival. Except in the case of fraud, all claims for indemnification for breach of representations and warranties under Section 10.1(b) and 10.2(b) shall be extinguished and be of no further force and effect on the date that is [***] months following the Closing Date; provided, however, that any claim for indemnification made in writing by the Indemnified Party under Section 10.5.1 on or prior to the expiration of such [***] month period shall survive until such claim is finally and fully resolved; and *provided, further,* that, notwithstanding anything herein to the contrary, the Fundamental Warranties and all corresponding claims for indemnification shall remain in full force and effect and shall survive indefinitely. All of the covenants and agreements contained in this Agreement that by their nature are required to be performed after the Closing shall survive the Closing until fully performed or fulfilled.

10.6. Other limitations. The liability of the Indemnifying Party pursuant to this Section 10 shall be subject to the following limitations:

(a) any Loss shall be calculated taking into account any net Tax benefit (determined on a "with" and "without" basis) that actually reduces current year Taxes or that has been received in cash; and

(b) the Indemnifying Party's liability shall be excluded to the extent the Loss is recovered by the Indemnified Party by way of insurance or from a Third Party.

10.7. Third Party Claims.

10.7.1. Notice of Claim. If any Third Party notifies an Indemnified Party with respect to any matter (a "**Third Party Claim**") which may give rise to an Indemnity Claim against an Indemnifying Party under this Section 10, then the Indemnified Party will promptly give written notice to the Indemnifying Party; *provided*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation under this Section 10, except to the extent such delay actually and materially prejudices the Indemnifying Party.

10.7.2. Assumption of Defense, etc. The Indemnifying Party will be entitled to participate in the defense of any Third Party Claim that is the subject of a notice given by the Indemnified Party pursuant to Section 10.7. In addition, the Indemnifying Party will have the right to defend the Indemnified Party against the Third Party Claim with counsel of its choice reasonably satisfactory to the Indemnified Party so long as (a) within fifteen (15) days after the Indemnified Party has given notice of the Third Party Claim requesting indemnification, the Indemnifying Party gives written notice to the Indemnified Party that the Indemnifying Party will indemnify the Indemnified Party from and against the entirety of any and all Losses the Indemnified Party may suffer resulting from, arising out of, relating to, in the nature of, or caused by the Third Party Claim, (b) the Indemnifying Party provides the Indemnified Party with evidence reasonably acceptable to the Indemnified Party that the Indemnifying Party will have adequate

financial resources to defend against the Third Party Claim and fulfill its indemnification obligations hereunder, (c) the Third Party Claim involves only money damages and does not seek an injunction or other equitable relief against the Indemnified Party, (d) the Indemnified Party has not been advised by counsel that an actual or potential conflict exists between the Indemnified Party and the Indemnifying Party in connection with the defense of the Third Party Claim, (e) the Third Party Claim does not relate to or otherwise arise in connection with the validity, enforceability or infringement of Intellectual Property, or any criminal or regulatory enforcement Action, and (f) the Indemnifying Party conducts the defense of the Third Party Claim actively and diligently. The Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense of the Third Party Claim, subject to the terms and conditions of this Section 10.

10.7.3. Limitations on Indemnifying Party. The Indemnifying Party will not consent to the entry of any judgment or enter into any compromise or settlement with respect to the Third Party Claim without the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned) unless such judgment, compromise or settlement (a) provides for the payment by the Indemnifying Party of money as sole relief for the claimant, (b) results in the full and general release of Rallybio Indemnified Persons or Prophylix Indemnified Persons, as applicable, from all liabilities arising or relating to, or in connection with, the Third Party Claim, (c) involves no finding or admission of any violation of Legal Requirements or the rights of any Person, and (d) will not prejudice any other claims that may be made against the Indemnified Party.

10.7.4. Indemnified Party's Control. If the Indemnifying Party does not deliver the notice contemplated by clause (a), or the evidence contemplated by clause (b), of Section 10.7.2 within fifteen (15) days after the Indemnified Party has given notice of the Third Party Claim, or otherwise at any time fails to conduct the defense of the Third Party Claim diligently, the Indemnified Party may defend, and to the extent permitted by Section 10.7.6, may consent to the entry of any judgment or enter into any compromise or settlement with respect to, the Third Party Claim in any manner it may deem appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), provided that the Indemnifying Party shall conduct the defense of the Third Party Claim actively and diligently. If such notice and evidence is given on a timely basis and the Indemnifying Party conducts the defense of the Third Party Claim diligently but any of the other conditions in Section 10.7.2 is or becomes unsatisfied, the Indemnified Party may defend, and may consent to the entry of any judgment or enter into any compromise or settlement with respect to, the Third Party Claim; *provided*, *however*, that the Indemnifying Party will not be bound by, or be obligated to provide indemnification solely by virtue thereof, the entry of any such judgment consented to, or any such compromise or settlement effected, without its prior written consent (which consent will not be unreasonably withheld or delayed).

10.7.5. In the event that the Indemnified Party conducts the defense of the Third Party Claim pursuant to Section 10.7.4, the Indemnifying Party will remain responsible for any and all other Losses that the Indemnified Party may incur or suffer resulting from, arising out of, relating to, in the nature of or caused by the Third Party Claim to the fullest extent provided in this Section 10.

10.7.6. Limitations on Indemnified Party. If the Indemnified Party controls such defense, the Indemnified Party will not consent to the entry of any judgment or enter into any compromise or settlement with respect to the Third Party Claim without the prior written consent of the Indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned) if such judgment, compromise or settlement (a) does not result in the full and general release of Rallybio Indemnified Persons and Prophylix Indemnified Persons from all liabilities arising or relating to, or in connection with, the Third Party Claim, (b) involves a finding or admission of Prophylix Indemnified Persons or Rallybio Indemnified Persons of any violation of Legal Requirements or the rights of any Person, or (c) prejudices the Indemnifying Party's defense against any other claims that may be made against the Indemnifying Party.

10.7.7. Consent to Jurisdiction Regarding Third Party Claim. Rallybio and Prophylix, each in its or their capacity as an Indemnifying Party, hereby consents to the non-exclusive jurisdiction of any court in which any Third Party Claim may be brought against any Indemnified Party for purposes of any claim which such Indemnified Party may have against such Indemnifying Party pursuant to this Agreement in connection with such Third Party Claim.

10.8. Losses Net of Insurance; Mitigation. The waiver of any condition contained in this Agreement or any Transfer Agreement based on the breach of any such representation or warranty, or on the performance of or compliance with any such covenant or agreement, will not affect the right of any Rallybio Indemnified Person or Prophylix Indemnified Person to indemnification pursuant to this Section 10 based on such representation, warranty, covenant or agreement.

10.9. Waiver of Claims. Each Party agrees and undertakes that (in the absence of fraud or willful misconduct) it has no rights against and shall undertake to irrevocably waive any right to make any claims against any employee, board member, officer, agent, adviser or Representative of the other Party in connection with this Agreement and the Contemplated Transaction (each a "**Protected Party**"). Furthermore, each Party shall procure that its respective Affiliates, and that any of its Representatives or its Affiliates Representatives, do not make or pursue any such claim. In the event of any breach of this Section 10.9, the breaching Party shall indemnify and hold such Protected Party harmless from any Loss caused by such breach.

10.10. Remedies Cumulative. The rights of each Rallybio Indemnified Person and Prophylix Indemnified Person under this Section 10 are cumulative, and each Rallybio Indemnified Person and Prophylix Indemnified Person, as the case may be, will have the right in any particular circumstance, in its sole discretion, to enforce any provision of this Section 10 without regard to the availability of a remedy under any other provision of this Section 10. The rights of each Rallybio Indemnified Person and each Prophylix Indemnified Person under this Section 10 shall be cumulative with any rights contained in the Transfer Agreements.

10.11. Sole Remedies. The Parties hereto acknowledge and agree that except as for claims based on an act of fraud or intentional misrepresentation, the indemnification provisions of this Section 10 shall be the sole and exclusive remedy for any item that is covered by such indemnification provisions.

10.12. Adjustment to Purchase Price. Any payments made to an Indemnified Party pursuant to this Section 10 shall be treated as an adjustment to the Purchase Price (as determined for Tax purposes), except as otherwise required by applicable Legal Requirements.

10.13. LIMITATION ON REMEDIES. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY OR ANY AFFILIATE OF THE OTHER PARTY FOR LOST REVENUES OR LOST PROFITS OR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER, EXCEPT (I) TO THE EXTENT THAT SUCH DAMAGES WERE ACTUALLY PAID TO A THIRD PARTY PURSUANT TO A THIRD PARTY CLAIM OR (II) WITH RESPECT TO CLAIMS OF COMMON LAW FRAUD OR INTENTIONAL MISREPRESENTATION.

11. TAX MATTERS.

11.1. Tax Allocation. The Purchase Price (as determined for Tax purposes) will be allocated among the Acquired Assets in accordance with Section 1060 of the Code as set forth on Schedule 11.1; provided, that within thirty (30) days following the Closing Date and upon written notice to Prophylix, Rallybio may reasonably revise Schedule 11.1 after consultation with its tax and accounting Representatives. The parties each hereby agree to prepare their respective Tax Returns consistent with this allocation, as revised (if applicable). This obligation shall survive the Closing.

11.2. Transfer Taxes. All transfer, bulk sales, stamp, documentary, sales, use, registration, value-added and other similar Taxes (including all applicable real estate transfer Taxes) and related penalties, interest and additions to Taxes incurred in connection with this Agreement and the transactions contemplated hereby ("**Transfer Taxes**") (including any domestic federal, state, local or similar Taxing Authority) will be borne equally (50%/50%) by each of the Parties.

11.3. Reasonable Cooperation. Prophylix and Rallybio, at their own respective costs, shall provide reasonable cooperation and information to each other in connection with (i) the preparation or filing of any Tax Return with respect to the Acquired Assets.

11.4. Reimbursement of Taxes. Upon receipt of any bill for Taxes described in Section 11.2 or any Taxes relating to the Acquired Assets or the Products relating to the period prior to the Closing, the recipient Party shall present a statement to the other setting forth the amount of such reimbursement to which the recipient Party is entitled together with such supporting evidence as is reasonably necessary to calculate the proration amount. Any amount shall be paid within ten (10) days after delivery of such statement.

12. MISCELLANEOUS

12.1. Notices. All notices, requests, demands, claims and other communications required or permitted to be delivered, given or otherwise provided under this Agreement must be in writing and must be delivered, given or otherwise provided:

(a) by hand (in which case, it will be effective upon delivery);

(b) by e-mail if also delivered by overnight delivery by a nationally recognized courier service (in which case, it will be effective on the Business Day after being deposited with such courier service); or

(c) by overnight delivery by a nationally recognized courier service (in which case, it will be effective on the Business Day after being deposited with such courier service);

in each case, to the address (or e-mail address) listed below: If to Prophylix, to it at:

Prophylix AS
Forskningsparken, Sykehusvegen 23
9019 Tromsø, Norway
Attention: Marit Wick
Email: [***]

with a copy to (which shall by itself not constitute notice to Prophylix for any purposes under this Agreement):

Advokatfirmaet Schjødt AS
Ruseløkkveien 14/P.O. Box 2444 Solli
0201 Oslo, Norway
Attention: Tord Fondevik
Email: tofo@schjodt.no

and

DLA Piper LLP (USA)
1650 Market St., Suite 5000
Philadelphia, PA 191030
Attention: Fahd M.T. Riaz
Email: fahd.riaz@dlapiper.com

If to Rallybio, to it at:

Rallybio IPA, LLC
400 Farmington Avenue, Suite R2818
Farmington, CT 06032
Attention: Jeffrey Fryer
Email: [***]

with a copy to (which shall by itself not constitute notice to Rallybio for any purposes under this Agreement):

Wiggin and Dana LLP
Two Stamford Plaza
281 Tresser Boulevard
Stamford, Connecticut 06901
Email Address: pmelick@wiggin.com; ekipperman@wiggin.com
Attention: Patti Melick
Evan Kipperman

Each of the Parties to this Agreement may specify a different address or e-mail address by giving notice in accordance with this Section 12.1 to each of the other Parties hereto.

12.2. Succession and Assignment; No Third-Party Beneficiary. Subject to the immediately following sentence, this Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, each of which such successors and permitted assigns will be deemed to be a party hereto for all purposes hereof. No Party may assign, delegate or otherwise transfer either this Agreement or any of its rights, interests, or obligations hereunder without the prior written approval of the other Party; *provided*, *however*, that (a) after the Closing, Prophylix may (i) assign to any of its Affiliates or (ii) assign or transfer its rights to receive payments under this Agreement (but no liabilities or other rights), without Rallybio's consent, to an Affiliate or to a Third Party in connection with a payment factoring transaction, in each case, so long as Prophylix is not relieved of any Liability hereunder, and (b) after the Closing, Rallybio may (i) assign any or all of its rights and obligations hereunder to any of its Affiliates, to any purchaser of all or substantially all of its assets or all or substantially all of its assets to which this Agreement relates or to any successor corporation resulting from any merger, consolidation, share exchange, reorganization, or other similar transaction, (ii) designate one or more of its Affiliates to perform its obligations hereunder, or (iii) assign any or all of its rights and obligations hereunder to any lender to Rallybio or any of its Affiliates as collateral security, in each case, without Prophylix's consent, provided that no such assignment shall relieve Rallybio of its obligations hereunder. Any purported assignment or transfer made in contravention of this Section 12.2 will be null and void.

12.3. Amendments and Waivers. No amendment or waiver of any provision of this Agreement will be valid and binding unless it is in writing and signed, in the case of an amendment, by Rallybio and Prophylix, or in the case of a waiver, by the Party against whom the waiver is to be effective. No waiver by any Party of any breach or violation or, default under or inaccuracy in any representation, warranty or covenant hereunder, whether intentional or not, will be deemed to extend to any prior or subsequent breach, violation, default of, or inaccuracy in, any such representation, warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. No delay or omission on the part of any Party in exercising any right, power or remedy under this Agreement will operate as a waiver thereof.

12.4. Entire Agreement. This Agreement, together with the Transfer Agreements and any documents, instruments and certificates explicitly referred to herein or therein, constitutes the entire agreement among the Parties hereto with respect to the subject matter hereof and supersedes any and all prior discussions, negotiations, proposals, undertakings, understandings and agreements, whether written or oral, with respect to such subject matter.

12.5. Counterparts. This Agreement may be executed in any number of counterparts, including facsimile or electronic copies thereof (e.g., portable document format (PDF)), each of which will be deemed an original, but all of which together will constitute but one and the same instrument. This Agreement will become effective when duly executed by each Party hereto.

12.6. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction will not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. In the event that any provision hereof would, under applicable Legal Requirements, be invalid or unenforceable in any respect, each Party hereto intends that such provision will be construed by modifying or limiting it so as to be valid and enforceable to the maximum extent compatible with, and possible under, applicable Legal Requirements.

12.7. Headings. The headings contained in this Agreement are for convenience purposes only and will not in any way affect the meaning or interpretation hereof.

12.8. Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement. The Parties intend that each representation, warranty and covenant contained herein will have independent significance. If any Party has breached or violated, or if there is an inaccuracy in, any representation, warranty or covenant contained herein in any respect, the fact that there exists another representation, warranty or covenant relating to the same subject matter (regardless of the relative levels of specificity) which the Party has not breached or violated, or in respect of which there is not an inaccuracy, will not detract from or mitigate the fact that the Party has breached or violated, or there is an inaccuracy in, the first representation, warranty or covenant.

12.9. Governing Law. This Agreement, the rights of the Parties and all Actions arising in whole or in part under or in connection herewith, will be governed by and construed in accordance with the domestic substantive laws of the State of New York, without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction. Each Party submits to the exclusive jurisdiction of the federal and state courts of the located in the Southern District of New York (and any appellate court from any thereof) in any action or proceeding arising out of or relating to this Agreement or the Contemplated Transaction, including recognition or enforcement of any judgment.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as an agreement under seal as of the Execution Date.

RALLYBIO IPA, LLC

By: /s/ Stephen Uden
Name: Stephen Uden
Title: COO

PROPHYLIX AS

By: /s/ Søren Weis Dahl
Name: Søren Weis Dahl
Title: Chief Executive Officer

Exhibit 1

Definitions

As used herein, the following terms will have the following meanings:

"**Accessed Party**" is defined in Section 6.3.

"**Accessing Party**" is defined in Section 6.3.

"**Acquired Assets**" is defined in Section 2.1.

"**Acquired Intellectual Property**" is defined in Section 2.1(c).

"**Acquisition**" means the purchase and sale of the Acquired Assets and the assumption of the Assumed Liabilities.

"**Acquisition Proposal**" is defined in Section 6.4.

"**Action**" means any Claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding to, from, by or before any Governmental Authority; *provided*, *however*, that Patent prosecution in the Ordinary Course of Business before the U.S. Patent and Trademark Office, corresponding foreign patent offices and under the Patent Cooperation Treaty, shall not be considered an "Action".

"**Affiliate**" of an entity means any other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such first entity. For purposes of this definition only, "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means the possession of the actual power to direct the management or policies of an entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

"**Agreement**" is defined in the Preamble.

"**Assumed Contracts**" is defined in Section 2.1(d).

"**Assumed Liabilities**" is defined in Section 2.4.

"**Bill of Sale and Assignment and Assumption Agreement**" means the Bill of Sale and Assignment and Assumption Agreement to be entered into between Rallybio and Prophylix, which shall be in the form of Exhibit A.

"**BLA**" means any Biologics License Application as defined in the PHSA.

"**Business Day**" means any weekday other than a weekday on which banks in the State of New York are authorized or required to be closed.

"**Calendar Quarter**" means any of the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, or the applicable part thereof.

"**Calendar Year**" means any calendar year ending on December 31, or the applicable part thereof.

"**Claim**" means any assertion of right whatsoever (including all Debts, bonds, promises, damages, equitable claims and judgments), whether liquidated, fixed or contingent, direct or indirect, or imputed.

"**Closing**" is defined in Section2.7.

"**Closing Date**" means the date on which the Closing actually occurs.

"**Closing Payment**" is defined in Section 3.1.

"**Code**" means the U.S. Internal Revenue Code of 1986, as amended.

"**Commercially Reasonable Efforts**" means those efforts, [***].

"**Confidential Disclosure Agreement**" is defined in Section 6.6.

"**Contemplated Transactions**" means, collectively, the transactions contemplated by this Agreement, including (a) the Acquisition and (b) the execution, delivery and performance of this Agreement and the Transfer Agreements.

"**Contractual Obligation**" means, with respect to any Person, any contract, agreement, deed, mortgage, lease, license, commitment, promise, undertaking, arrangement or understanding that is legally binding, whether written or oral and whether express or implied, or other document or instrument (including any document or instrument evidencing or otherwise relating to any Debt) to which or by which such Person is a party or otherwise subject or bound or to which or by which any property, business, operation or right of such Person is subject or bound.

"**Control**" or "**Controlled**" means possession of the ability to grant a license or sublicense hereunder without violating the terms of any agreement with any Third Party.

"**Copyrights**" means all copyrights and copyrightable works, whether published or unpublished, including all rights of authorship, use, publication, reproduction, distribution, performance and public display, transformation, moral rights and rights of ownership of copyrightable works and all rights to register and obtain renewals and extensions of registrations, rights to make derivative works based on the foregoing together with all other interests accruing by reason of United States or international copyright law.

"**Debt**" means, with respect to any Person, all obligations (including all obligations in respect of principal, accrued interest, penalties, fees and premiums) of such Person (a) for borrowed money (including overdraft facilities), (b) evidenced by notes, bonds, debentures or similar Contractual Obligations, (c) for the deferred purchase price of property, goods or services (other than trade payables or accruals incurred in the Ordinary Course of Business), (d) under capital leases (in accordance with IFRS), (e) in respect of letters of credit and bankers' acceptances, (f) for Contractual Obligations relating to interest rate protection, swap agreements and collar agreements or (g) in the nature of guarantees of the obligations described in clauses (a) through (f) above of any other Person.

"**Drop Dead Date**" is defined in Section 9.1(e).

"**EMA**" means the European Medicines Agency and any successor entity thereto.

"**[***]**" is defined in Section 3.2.

"**[***]**" is defined in Section 3.2.

"**Enforceable**" means, with respect to any Contractual Obligation stated to be enforceable by or against any Person, that such Contractual Obligation is a legal, valid and binding obligation of such Person enforceable by or against such Person in accordance with its terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors and to general principles of equity (regardless of whether enforceability is considered in a proceeding in equity or at law).

"**Excluded Assets**" is defined in Section 2.2.

"**Excluded Liabilities**" is defined in Section 2.5.

"**Execution Date**" is defined in the Preamble to this Agreement.

"**FDA**" is defined in Section 4.10.2(a).

"**FDCA**" is defined in Section 4.10.2(a).

"**Financial Statements**" is defined in Section 4.5.

"**First Commercial Sale"** means, on a Product-by-Product, and country-by-country basis, the first sale of such Product by Rallybio or an Affiliate or licensee of Rallybio to a Third Party for end use or consumption in such country after Regulatory Approval has been granted with respect to such Product in such country; *provided,* that "**First Commercial Sale**" shall not include (a) [***].

"**Fundamental Warranties**" means the representations and warranties of Prophylix or Rallybio, as the case may be, in Section 4.1 (Organization), Section 4.2 (Power and Authorization), Section 4.8 (Acquired Assets), Section 4.10.4 (Data Protection Compliance), Section 4.15 (No Brokers), Section 4.17 (Taxes), Section 4.19 (Solvency; Fraudulent Conveyance), Section 5.1 (Organization), Section 5.2 (Power and Authorization), and Section 5.6 (No Brokers).

"**Governmental Authority**" means any United States federal, state or local or any foreign government, or political subdivision thereof, or any local, state, national or multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any arbitrator or arbitral body.

"**Governmental Authorization**" means all investigational new drug applications, new drug applications, abbreviated new drug applications, new drug submissions, drug master files, any comparable applications and submissions or certifications, together or combined with any and all supplements or modifications or amendments thereto, whether existing, pending or withdrawn, together with all correspondence to or from any Governmental Authority with respect thereto and any other Permits, prepared and submitted or in preparation for submission to any Governmental Authority, in each case solely relating to the Products.

"**Governmental Order**" means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority that is binding on any Person or any of its property under any Legal Requirement.

"**Guarantee"** means the Guarantee to be entered into by Rallybio Holdings, LLC and Prophylix, which shall be in the form attached hereto as Exhibit C.

"**IFRS**" means International Financial Reporting Standards consistently applied.

"**Inbound License Agreements**" is defined in Section 4.9.1(d).

"**Indemnified Party**" means, with respect to any Indemnity Claim, the Party asserting such claim under Section 10.1 or Section 10.2, as the case may be.

"**Indemnifying Party**" means, with respect to any Indemnity Claims, Rallybio or Prophylix under Section 10.1 or Section 10.2, as the case may be, against whom such claim is asserted.

"**Indemnity Claim**" means a claim for indemnity under Section 10.1 or Section 10.2, as the case may be.

"**Insurance Policies**" is defined in Section 4.13.

"**Intellectual Property**" means any and all of the following in any country: Copyrights, Patents, Trademarks, domain name registrations, Trade Secrets, Know-How rights, software (including source code and object code), data or other exclusivity rights, all inventions whether or not patentable, and any other intellectual property rights of any kind or nature whether owned, licensed or otherwise held.

"IPR Assignment Agreement" is defined in Section 7.7.

"**Know-How**" means inventions, technical information, know-how and materials, including technology, data, compositions, formulas, biological materials, assays, reagents, constructs, compounds, discoveries, procedures, processes, practices, protocols, methods, techniques, results of experimentation or testing, knowledge, trade secrets, skill and experience, in each case whether or not patentable or copyrightable, and in each case that are unpatented.

"**Legal Requirement**" means, with respect to any Person, any United States federal, state or local or foreign law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, judicial interpretation, or any Governmental Order, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law applicable to any of such Person or any of such Person's property, assets, Affiliates or Representatives.

"**Liability**" means, with respect to any Person, any liability or obligation of such Person whether known or unknown, whether asserted or un-asserted, whether determined, determinable or otherwise, whether absolute or contingent, whether accrued or un-accrued, whether liquidated or unliquidated, whether incurred or consequential, whether due or to become due and whether or not required under IFRS to be accrued on the financial statements of such Person.

"**Lien**" means any mortgage, pledge, lien, security interest, charge, Claim, condition, (solely with respect to the Patents listed on Schedule 2.1(c), any out-bound license), covenant not to sue, option, right of first offer or refusal, buy/sell agreement, equitable interest, encumbrance, restriction on transfer, conditional sale or other title retention device or arrangement (including a capital lease), transfer for the purpose of subjection to the payment of any Debt, or restriction on the creation of any of the foregoing or any other restriction or covenant with respect to, or condition governing the use, construction, transfer, receipt of income or exercise of any other attribute of legal or equitable ownership, whether relating to any property or right or the income or profits therefrom.

"**Losses**" is defined in Section 10.1.

"**Marketing Authorization Application"** means an application for the authorization to market a Product in any particular country or regulatory jurisdiction, as defined in the applicable Legal Requirements and filed with the applicable Governmental Authority of such country or regulatory jurisdiction, including any BLAs.

"**Material Adverse Effect**" means any change in, or effect on, (i) the Acquired Assets or the Products, or (ii) Prophylix, which, when considered either individually or in the aggregate together with all other adverse changes or effects with respect to which such phrase is used in this Agreement is, or is reasonably likely to be, materially adverse to (a) the Acquired Assets or the developing, manufacturing, making, using, selling, offering for sale, importing, exporting or other exploitation of the Products taken as whole or (b) Prophylix's ability to perform under or to consummate the Contemplated Transactions; *provided*, *however*, that (1) changes in economic or political conditions or the financing, banking, currency or capital markets in general, (2) conditions affecting the industries and markets in which Prophylix participates or the economic or political circumstances or financing, banking, currency or capital markets in general, (3) acts of war (whether or not declared), armed hostilities or terrorism, or the escalation or worsening thereof, (4) any changes in applicable Legal Requirements or accounting rules, including IFRS, (5) changes or effects that arise out of or attributable to the public announcement of the Contemplated Transactions, or (6) any failure of Rallybio to meet its or Prophylix's internal projections related to the Acquired Assets (including, without limitation, any internal projections related to development or commercialization timelines, regulatory milestones, and sales projections), shall not be deemed to be and shall not be taken into account in determining whether there has been or will be a Material Adverse Effect, unless with respect to items (1) through (3), such conditions or events have a disproportionate effect on the Acquired Assets or the Products compared to other participants in the industries in which Prophylix operates.

"**Milestone Payment 2**" is defined in Section 3.3.1.

"**Milestone Payment 3**" is defined in Section 3.3.1.

"**NAITgam**" means Prophylix's plasma-derived anti-HPA-1a immunoglobulin as more specifically described on Schedule 1.

"Net Sales" means the gross amount collected by Rallybio, its Affiliates and licensees from Third Parties for sales of Products for fetal neonatal alloimmune thrombocytopenia (FNAIT, NAITP, NAIT, NATP or NAT) prophylaxis or therapy, after deduction of allowances, to the extent included in the gross invoiced sales price for such Product, stated separately on the invoice, or actually incurred by the selling party, for:

(a) [***];

(b) [***];

(c) [***], and

(d) [***].

Net Sales shall be consistently applied by Rallybio and its Affiliates for all other products (except as otherwise contemplated in this definition of Net Sales).

For the avoidance of doubt, sales between or among Rallybio and its Affiliates or licensees will be excluded from the computation of Net Sales. All such discounts, allowances, credits, rebates and other deductions shall be fairly and equitably allocated to the Products and other products or services of Rallybio or its licensees, such that the Products do not bear a disproportionate portion of such deductions. The Parties acknowledge and agree that there shall be no double-counting in determining the foregoing deductions from gross amounts invoice to calculate "Net Sales" hereunder. In any sale or other disposal of a Product otherwise than in an arm's length transaction exclusively for money, Net Sales shall be valued at the fair market value of the consideration received as agreed by the Parties. Notwithstanding the foregoing, transfers or dispositions of Products (x) in connection with patient assistance programs, (y) for charitable or promotional purposes, or (z) for preclinical or clinical trial purposes or under so-called "named patient" or other limited access programs, shall not, in each case, result in Net Sales or constitute a First Commercial Sale of such Product to the extent that Rallybio, its Affiliates or licensees do not receive compensation for such transfers or dispositions in excess of Rallybio, its Affiliates or licensees' cost for such Product.

In the case of any product that contains any Product(s) in combination with any other clinically active ingredient(s) that is not NAITgam or a T1 Antibody, whether packaged together and sold for a single price, in the same formulation or sold together for a single price (a "**Combination Product**") in any country, Net Sales for such Combination Product in such country shall be calculated as follows: [***].

"**Ordinary Course of Business**" means an action taken by any Person in the ordinary course of such Person's business which is consistent with the past customs and practices of such Person, and, with respect to the Acquired Assets or the Products, the past customs and practices of Prophylix (including past practice with respect to quantity, amount, magnitude and frequency).

"**Organizational Documents**" means, with respect to any Person (other than an individual), (a) the certificate or articles of association, incorporation or organization and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, voting agreements and similar documents, instruments or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

"**Party**" and "**Parties**" are each defined in the Preamble.

"**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of the foregoing, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications and any and all rights to claim priority from any of the foregoing, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

"**Patent Assignment**" means the Patent Assignment to be executed and delivered by Prophylix, which shall be in the form of Exhibit B.

"**Permits**" means, with respect to any Person, any license that is not a license under Intellectual Property, franchise, permit, consent, approval, right, privilege, certificate or other similar authorization issued by, or otherwise granted by, any Governmental Authority or any other Person to which or by which such Person is subject or bound or to which or by which any property, business, operation or right of such Person is subject or bound.

"**Person**" means any individual or corporation, association, partnership, limited liability company, joint venture, joint stock or other company, business trust, trust, organization, Governmental Authority or other entity of any kind.

"**Pivotal Study**" means a pivotal study (whether or not designated a "Phase 2b" or "Phase 3" clinical study under applicable regulations) in human patients with a defined dose or set of defined doses of a Product designed to ascertain the efficacy and safety of such Product for the direct purpose and intent of enabling the preparation and submission of Marketing Authorization Applications to the applicable Governmental Authorities in a country in the Territory should the data from such study support the Marketing Authorization Application, as further defined in 21 C.F.R. 312.21(c), as amended from time to time, or the corresponding foreign regulations. For clarity, a Phase 2 or Phase 2b study intended as a Phase 3 enabling study shall not be deemed a Pivotal Study.

"**Priority Review"** means a priority review of and action upon a human drug application by the FDA not later than six months after the filing of such application to the FDA, as defined in the FDCA; and "**Priority Review Voucher"** means a priority review voucher issued by the U.S. Secretary of Health and Human Services that entitles the holder of such voucher to Priority Review of a single human drug application submitted under Section 505(b)(1) of the FDCA or a single biologic application submitted under Section 351(a) of the means the PHSA.

"**Products**" means all pharmaceutical compositions, formulations, dosage forms, delivery systems and presentations that contain NAITgam or a T1 Antibody.

"**Products Intellectual Property**" means (i) the Acquired Intellectual Property, and (ii) the licensed rights under the Inbound License Agreements listed on Schedule 4.9.1(d).

"**Prophylix**" is defined in the Preamble.

"**Prophylix Indemnified Person**" is defined in Section 10.2.

"**Prophylix's Knowledge**" and similar phrases means the actual knowledge of Søren Weis Dahl and Torgeir Vaage, after reasonable inquiry to Prophylix's outside patent counsel who prosecuted the Prophylix Patents and the executive employees of Prophylix.

"**Prophylix Patents**" means the Patents within the Acquired Intellectual Property listed on Schedule 4.9.1(a).

"**PHSA**" means the U.S. Public Health Service Act, as amended, and the rules and regulations promulgated thereunder.

"**Purchase Price**" is defined in Section 3.1.

"**Rallybio**" is defined in the Preamble.

"**Rallybio Indemnified Person**" is defined in Section 10.1.

"Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations (including any pricing and reimbursement approvals) of any country, federal, supranational, state or local Governmental Authority that are necessary for, as applicable, the development, manufacture, commercialization, or other exploitation of a Product in a given jurisdiction.

"**Representative**" means, with respect to any Person, any director, officer, employee, agent, consultant, contractor, advisor, or other representative of such Person, including legal counsel, accountants, and financial advisors.

"**Sign-On Fee**" means the payment of [***] NOK pursuant to Section 4.1(A) of the IPR Assignment Agreement.

"**T1 Antibody**" means the T1 monoclonal antibody and derivatives thereof included in the Acquired Assets and described in International Patent Publication No. WO 2015-150417 A1 as more specifically described on Schedule 1.

"**Tax**" or "**Taxes**" means (a) any and all federal, state, local, or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security (or similar, including FICA), unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or escheat liability or unclaimed property obligation, or other tax of any kind or any charge of any kind in the nature of (or similar to) taxes whatsoever, including any interest, penalty, or addition thereto, whether disputed or not and (b) any liability for the payment of any amounts of the type described in clause (a) of this definition as a result of being a member of an affiliated, consolidated, combined or unitary group for any period, as a result of any tax sharing or tax allocation agreement, arrangement or understanding, or as a result of being liable for another Person's taxes as a transferee or successor, by contract or otherwise.

"**Tax Return**" means any return, declaration, report, claim for refund or information return or statement relating to Taxes supplied or required to be supplied to a Taxing Authority, including any schedule or attachment thereto, and including any amendment thereof.

"**Taxing Authority**" means any Taxing Authority having jurisdiction with respect to any Tax.

"**Termination Date**" is defined in Section 9.1.

"**Territory**" means worldwide.

"**Third Party**" means a Person other than the Parties, their respective Affiliates and their employees.

"**Third Party Claim**" is defined in Section 10.7.1.

"**Trademarks**" means any word, name, symbol, color, designation or device or any combination thereof for use in the course of trade, including any trademark, registered trademark, application for registration of trademark, service mark, trade dress, brand mark, trade name, registered trade name, application for registration of trade name, brand name, domain name, logo or business symbol.

"**Trade Secrets**" means all confidential information and trade secrets such as confidential know-how, inventions, discoveries, improvements, concepts, ideas, methods, processes, designs, plans, schematics, drawings, formulae, technical data, specifications, research and development information, technology and product roadmaps, data bases.

"**Transaction Expenses**" is defined in Section 6.5.

"**Transfer Agreements**" means the Bill of Sale and Assignment and Assumption Agreement and the Patent Assignment.

"**Transferred Governmental Authorizations**" is defined in Section 2.1(a).

"**Transfer Taxes**" is defined in Section 11.2.

"**Treasury Regulations**" means the regulations promulgated under the Code.

"Tromsø License" is defined in Section 7.7.

"Valid Claim" means on a country by country basis (a) a claim of any issued, unexpired patent included in the Products that has not been revoked or held unenforceable or invalid by a decision of a court or Governmental Authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending or published Patent application included in

the Products that has not been cancelled, withdrawn or abandoned and that has not been pending for more than eight (8) years from the filing date of the earliest Patent application that is within the same Patent family as such pending or published application. For purposes of clarification, if a claim in an application has been pending for more than six (6) years from the earliest such pending or published application within the same such Patent family's priority date, and a Patent subsequently issues containing such claim, then upon issuance of the Patent, the claim shall thereafter be considered a Valid Claim.

"**Withholding Party**" is defined in Section 2.8.

EXHIBIT 10.2

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

ASSET TRANSFER AGREEMENT

by and between

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

and

IPC RESEARCH, LLC

DATE: 15 MARCH 2019

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SCHEDULES

Schedule 1	The Assets
Schedule 2	The Program
Schedule 3	Confirmatory Patent Assignment Schedule 4 Third Party Contracts
Schedule 5	Notice to University of Oslo
Schedule 6	Notice to University of Queensland
Schedule 7	Contract Assignment Agreement -Affibody ROA and PLA
Schedule 8	Strain and Plasmid Technology

This Asset Transfer Agreement (the "Agreement") is made effective as of 15 March 2019 (the "Effective Date") by and between

(1) Swedish Orphan Biovitrum AB (Publ), a company incorporated in Sweden under no. 556038-9321 with offices at S-112 76 Stockholm, Sweden ("Sobi") and

(2) IPC Research, LLC, a company incorporated in Delaware, USA, with offices at c/o Grimes & Yvon LLP, 800 Third Ave., 28th Floor, New York, NY 10022 ("IPC").

Recitals

(A) WHEREAS, Sobi is engaged in the research and development of novel biopharmaceutical drugs that work as inhibitors of complement protein C5 (the "Program") in relation to which Sobi has identified a number of compounds, including those encoded as SOBI002 and SOBI005;

(B) WHEREAS, Sobi exclusively owns or controls all assets, including the abovementioned compounds, pertaining to the Program.

(C) WHEREAS, Sobi desires to sell to IPC – and IPC desires to purchase from Sobi – the aforesaid assets on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. **Definitions**

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

1.1. "**Affibody**" means Affibody AB, Gunnar Asplunds Allé 24, 171 63 Solna, Sweden, and all its Affiliates.

1.2. "**Affibody Agreements**" means the following agreements by and between Sobi and Affibody, as some of them subsequently have been amended, (i) the Research Collaboration and Option Agreement effective as of 23 March 2009 (the "**Affibody ROA**"); (ii) the Product License Agreement related to the Program effective as of 9 March 2012 (the "**Affibody PLA**"); (iii) the Letter Agreement dated 4 November 2015 (the "**[***] Agreement**"); (iv) the Letter Agreement dated 20 October 2014 (the "**[***] Letter Agreement**"); and (v) the Material Transfer Agreement dated 30 November 2016 (the "**[***] MTA**").

1.3. "**Affiliate**" means, with respect to a Person, any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. For the purpose of this definition only, the term "control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such Person.

1.4. "**Annual Net Sales**" means the Net Sales made during a given Calendar Year.

1.5. "**Asset List**" means the asset list attached hereto as Schedule 1.

1.6. "**Assignable Third Party Contract(s)**" means the Affibody ROA, the Affibody PLA, the **[***]** MTA and the **[***]** MTA, some of which have expired with certain surviving terms and conditions.

1.7. "**Assets**" means the Patent Rights (including without limitation Transferred Patents), the Compounds, the Materials, the Know-How, the Data, the Assignable Third Party Contracts, and the Records as well as any other assets listed in the Asset List. For avoidance of doubt, Sobi's proprietary Elvera™ platform technology is not part of the Assets and no license to the said technology is granted hereunder. For the avoidance of doubt, the Affibody Agreement and Sobi's rights thereunder are included in the Assets, but the intellectual property licensed to Sobi under the Affibody Agreement remains licensed and is not part of the Assets.

1.8. "**Business Day**" means a day (other than a Saturday or Sunday) on which banks are open for business in Sweden.

1.9. "**C5-inhibitor**" means a biopharmaceutical drug or compound that works as an inhibitor of complement protein C5. [***]

1.10. "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on 1st January, 1st April, 1st July and 1st October.

1.11. "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on 1st January.

1.12. "**[***]**" means "the **[***]**" sponsored by [***] and certain Swedish universities and companies, including Sobi.

1.13. "**[***] Agreement**" means the [***] agreement entitled "[***]" effective as of January 1, 2018 to which Sobi is a party.

1.14. "**[***] Results**" means any [***] Results or [***] Results (as these terms are defined in the [***] Agreement) generated in [***] and Controlled by Sobi on the Effective Date.

1.15. "**Commercially Reasonable Efforts**" or "**CRE**" means, [***].

1.16. "**Compound Product**" means a product that contains a Compound as active ingredient.

1.17. "**Compound(s)**" means (i) all compounds specified in the Asset List, (ii) all compounds described, covered or claimed by any of the Transferred Patents (although not specified in the Asset List), and (iii) all compounds other than (i) or (ii) being C5-inhibitors discovered, conceived, reduced to practice or otherwise generated by or on behalf of Sobi in connection with the Program prior to the Effective Date. To assess the half-life extension properties of Sobi's proprietary Elvera™ platform technology Sobi has, outside of the Program, generated C5-inhibitor compounds that utilize the said platform technology. For avoidance of doubt, no such compounds shall be deemed Compounds hereunder and, consequently, are not included in the Assets.

1.18. "**Confidential Information**" means (a) the existence and contents of this Agreement and (b), subject to Section 13, any information relating to a Party's or its Affiliates' business, research or development activities – including any trade secrets and any scientific, technical, financial or business information – disclosed or made available by or on behalf of a Party or any of its Affiliates to the other Party or any of its Affiliates in any form including, without limitation, oral and written form. After the Effective Date, information regarding the Assets shall be the Confidential Information of IPC.

1.19. "**Confirmatory Patent Assignment**" has the meaning set forth in Section 4.2.

1.20. "**Control**" means, with respect to any item of information or intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, licence or otherwise, to assign, or grant a licence, sublicense or other right to or under, such information or intellectual property right, as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.21. "**Data**" means all data arising from the operation of the Program up until the Effective Date including the results of all experimentation and testing and any preclinical data.

1.22. "**Distributor**" has the meaning set forth in Section 4.8.

1.23. "**Effective Date**" is defined in the introduction of this Agreement.

1.24. "**Encumbrance**" means any interest of any Person other than the Parties, including any mortgage, charge, pledge, lien or other security interest of any kind, any licence, any right to acquire, or any option or right of pre-emption.

1.25. "**Exempt Third Party Products**" means any product containing a C5- inhibitor that is owned or Controlled by a Third Party and that has been approved by the applicable Health Authority for marketing in any country of the Territory prior to the Effective Date or that is so approved during the [***] (as defined in Section 8.1). An Exempt Third Party Product shall include any non-approved product containing the same active ingredient as the approved Exempt Third Party Product (but e.g. having a different formulation, dosage form, strength, use, indication or otherwise is a line extension of the Exempt Third Party Product). For clarity, [***] and [***] are the only Exempt Third Party Products as at the Effective Date.

1.26. "**Exploit**" means to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of, a product or process and "**Exploitation**" means the act of Exploiting a product or process.

1.27. "**EU**" or "**European Union**" means the economic, scientific and political organization of European member states, as its membership exists as of the Effective Date, including without limitation, the United Kingdom.

1.28. "**Field**" means inhibition of complement protein C5.

1.29. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.30. "**First Commercial Sale**" means the first sale for monetary value for use or consumption by the general public of a Product in a particular country after Health Registration Approval for such Product has been obtained in such country. For the avoidance of doubt, sales prior to receipt of Health Registration Approval necessary to commence regular commercial sales in a country, such as so-called "treatment IND sales", "named patient sales" and "compassionate use sales", shall not be construed as a First Commercial Sale.

1.31. "**Force Majeure**" has the meaning set forth in Section 15.1.

1.32. "**Force Majeure Party**" has the meaning set forth in Section 15.1.

1.33. "**Health Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Compound or a Compound Product.

1.34. "**Health Registration Approval**" means, with respect to a particular country, any MAA and all approvals, licences, registrations or authorisations of any Health Authority necessary to commercially distribute, sell or market a Compound Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorisations (including any prerequisite Manufacturing approval or authorisation related thereto), (c) labelling approval and (d) technical, medical and scientific licences.

1.35. "**Indirect Taxes**" means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.36. "**Know-How**" means any unpatented technical and other information developed or arising from the conduct of the Program prior to the Effective Date, including inventions, discoveries, methods, processes and procedures, ideas, concepts, formulae, specifications, evaluations, analyses, procedures for experiments and tests, that is necessary or useful for understanding, practising, using or otherwise Exploiting the Transferred Patents and the inventions described therein, the Compounds or the Materials, including such information contained in or in relation to laboratory notebooks, the Records, experimental data, research summaries and reports, invention disclosures, and internal and external study results, manufacturing data, batch records, composition, method, trade secret, formula, protocol, technique or other data.

1.37. "**Knowledge**" shall mean the knowledge and good faith understanding of any given facts and information of a senior qualified person of Sobi as of the Effective Date after having performed a diligent investigation with respect to such facts and information immediately prior to the Effective Date.

1.38. "**Licensee**" has the meaning set forth in Section 4.7.

1.39. "**Loss**" means any and all liabilities, claims, demands, causes of action, damages, suits, costs, reduction of value, loss and expenses, including interest, penalties, and lawyers' fees and disbursements.

1.40. "**MAA**" or "**Marketing Authorization Application**" means an application for the authorization to market a product in any particular country or regulatory jurisdiction, as defined in applicable laws and filed with the applicable Health Authority of such country or regulatory jurisdiction, including any biologics license applications (BLAs).

1.41. "**Manufacture**" and "**Manufacturing**" means, with respect to a product or compound, the synthesis, manufacturing, processing, formulating, packaging, labelling, holding and quality control testing of such product or compound.

1.42. "**Materials**" means all physical quantities of the Compounds and all other materials that either (a) were used in the Program, except for materials that were not exclusively developed in or for the Program and can be applied also outside of the Program (e.g., commercially available reagents); or (b) are listed in part 2 of the Asset List.

1.43. "**Net Sales**" means the gross amounts received on a cash basis for sales of Products by IPC, its Affiliates and Licensees to Third Parties (including Distributors), after deduction of:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

[***].

1.44. "**Parties**" means IPC and Sobi and "**Party**" means either IPC or Sobi as the context requires.

1.45. "**[***] Agreement**" means the [***] agreement entitled "[***]" dated 2 January 2018, to which Sobi is a party.

1.46. "**[***] Results**" means any [***] Rights or [***] Foreground Rights (as these terms are defined in the [***] Agreement) generated under the [***] Agreement and Controlled by Sobi.

1.47. "**[***] MTA**" means the Research Collaboration Agreement dated 10 December 2014 by and between the [***] and Sobi, as amended.

1.48. "**[***]**" means [***] under the [***] Agreement.

1.49. "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, renewals and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents; and in each case, equivalents in countries other than the United States. For the purposes of clarity, the above definition of the term "Patent" applies to all other terms that incorporate the term "Patent," including, without limitation, the terms "Transferred Patent," "Subsequent Patent" and "Know-How Patents."

1.50. "**Patent Rights**" has the meaning set forth in Section 4.1.

1.51. "**Payments**" has the meaning set forth in Section 7.14.

1.52. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

1.53. "**Phase II Clinical Trial**" means exploratory clinical studies of a molecule in a limited number of humans to investigate efficacy and safety in the indication for which a product is intended, in order to provide proof of concept or to determine optimum efficacious dosing regimens. A Phase II Clinical Trial shall also include any combined Phase I/II or Phase II/III study or any Phase III study in lieu of a Phase II study, whether or not such study is a traditional Phase II study ("Seamless Phase I/II Study"). A Phase II Clinical Trial shall be deemed to have commenced when the first patient is dosed in such Phase II Clinical Trial.

1.54. "**Phase III Clinical Trial**" means a confirmatory clinical study in humans of the efficacy and safety of a product, which is designed to demonstrate whether such product is effective and safe for use in a particular indication. A Phase III Clinical Trial shall also include any combined Phase II/III study or any Phase II study in lieu of a Phase III study, whether or not such study is a traditional Phase III study ("Seamless Phase II/III Study"). A Phase III Clinical Trial shall be deemed to have commenced when the first patient is dosed in such Phase III Clinical Trial.

1.55. "**Product**" means a Compound Product for which Health Registration Approval has been obtained for sale – and which is marketed and sold – in the Territory.

1.56. "**Program**" means the research activities referred to in Recital (A) above, as further described in Schedule 2.

1.57. "**Program Asset**" has the meaning set forth in Section 3.5.

1.58. "**[***] MTA**" means the Material Transfer Agreement dated 24 December 2016 by and between the [***] and Sobi.

1.59. "**Records**" means the records listed in part 3 of the Assets List and all other laboratory notebooks, clinical and regulatory filings (if any), certifications, consents, approvals and other records, documents and files (whether in paper, electronic or other form) which contain information relating to the Program including Know-How, Data or information relating to the prosecution or maintenance of the Transferred Patents as well as any and all agreements with and assignments from the inventors of the inventions covered or claimed by the Transferred Patents.

1.60. "**Subsequent Patents**" has the meaning set forth in Section 4.1.2.

1.61. "**Third Party**" means any Person other than (i) the Parties, (ii) the Parties' respective Affiliates or (iii), in the case of IPC, its Licensees.

1.62. "T**hird Party Contract(s)**" has the meaning set forth in Section 6.1.

1.63. "**Territory**" means all countries in the world.

1.64. "**Transferred Patents**" means all of the Patents and Patent applications specified in part 1 of the Asset List (and all rights of priority with respect to such patent applications).

1.65. "**Valid Claim**" means, with respect to a Product in a particular country, any claim of a Patent included in the Patent Rights that (i) is Controlled by IPC or any of its Affiliates or Licensees, (ii) specifically or generically claims a Compound included in such Product as a composition of matter and (iii) either,

(a) with respect to a granted and unexpired Patent in such country, (AA) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal, and (BB) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or,

(b) with respect to a pending Patent application, was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, provided that such claim has not been pending for more than (a) seven (7) years if pending in a country other than Japan and (b) ten (10) years if pending in Japan.

2. **Construction**

Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The term "including" or "includes" as used in this Agreement means including, without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

3. **Sale, Transfer and License**

3.1. **Sale and Transfer of the Assets**. Upon the terms and conditions set forth in this Agreement, Sobi hereby sells and transfers and assigns to IPC as of the Effective Date, and IPC hereby purchases, assumes and takes over, as of such date, all of Sobi's right, title and interest in and to all of the Assets. Subject to Section 6.2, (i) IPC shall as per the Effective Date assume all revenues, costs, debts, liabilities, rights and obligations under the Assignable Third Party Contracts and expenses pertaining to the Assets that accrue on or after the Effective Date, including any future development or Patent costs; and (ii) Sobi shall remain responsible for all revenues, costs, debts, liabilities, rights and obligations under the Assignable Third Party Contracts and expenses pertaining to the Assets that accrued prior to the Effective Date. Sobi further grants to IPC a non-exclusive, perpetual, irrevocable and fully paid up license, with the right to grant sub-licenses, under Sobi's rights to the Strain and Plasmid Technologies specified in Schedule 8, as they exist on the Effective Date, for use solely in the Field.

3.2. Delivery of the Assets. Except to the extent otherwise set forth in this Agreement, Sobi shall within Thirty (30) Business Days after the Effective Date deliver to IPC all Assets that are capable of being physically delivered. Sobi shall deliver such Assets Ex Works (EXW), Sobi's premises in Stockholm (construed in accordance with Incoterms 2010). Transfer of electronic records will be performed as described in the Electronic Records Transfer Plan enclosed to Schedule 1.

3.3. Further Actions. Each of IPC and Sobi shall, from time to time and at its own cost, execute and deliver all such further instruments or documents and take all such further action as the other Party may reasonably request in order to consummate effectively the transfer of Assets contemplated by this Agreement.

3.4. In Man Testing. IPC acknowledges that the physical Compound quantities to be transferred hereunder by Sobi do not meet the regulatory standards for being tested or used in humans. IPC undertakes and warrants to Sobi that any such Compound quantities will not be used in humans in connection with clinical trials or otherwise without IPC first having (i) further processed such Compound quantities in a manner and/or taken such other actions required for the relevant Compound quantities to be brought up to and meet the applicable regulatory standards and (ii) having received prior written approval for use in humans from the relevant regulatory authorities in countries where the Compound quantities are intended to be used in humans.

3.5. Completeness of Assets; Assets Subsequently Identified. Sobi warrants that it has, prior to the Effective Date, undertaken a diligent search of all compounds, Patents, materials, records, data and other rights and assets relating exclusively to, used exclusively in or arising exclusively from research conducted by or on behalf of Sobi in relation to the Program prior to the Effective Date (collectively, "Program Assets"). The Assets and the rights acquired by IPC under this Agreement comprise all Program Assets, save for to the extent that any Assignable Third Party Contract or part thereof is not assigned or novated to IPC, provided that the Parties have complied with Section 6.2. All such Program Assets will be delivered to IPC pursuant to the terms of this Agreement. In the event that after the Effective Date Sobi (despite having conducted such diligent search) or IPC identifies any Program Asset which was not actually delivered to IPC as a result of the transactions carried out pursuant to this Agreement, then,

(i) in the event Sobi is the Party identifying such Program Asset, Sobi shall promptly notify IPC thereof in writing, and

(ii) regardless of which Party identified such Program Asset, Sobi shall at IPC's written request promptly transfer (or procure the transfer of) that Program Asset to IPC at Sobi's cost. The Program Asset shall be deemed to form part of the definition of Compounds, Transferred Patents, Materials, Data or Records (as appropriate) and by the definition of Assets.

4. Additional Provisions Regarding the Transferred Patents

4.1. Patent Rights. The transfer as per Section 3.1 includes all of Sobi's right, title and interest in and to the following rights (the "Patent Rights"), which are thus hereby assigned by Sobi to IPC as of the Effective Date to be held and enjoyed by IPC for its own use and for the use of its Affiliates, successors, licensees and assignees:

4.1.1. the Transferred Patents;

4.1.2. any and all Patents (the "Subsequent Patents") in any country that may be issued to or on any of the patent applications specified in the Asset List;

4.1.3. all of Sobi's right to make any patent applications – and all rights, title and interest in any patent application made – in any country in relation to any part of the Know-How (the "Know-How Patents"); and

4.1.4. any and all causes of action, claims, demands or other rights, occasioned from or because of any and all past and future infringement of any of the Transferred Patents, Subsequent Patents or Know-How Patents, including all rights to recover damages, profits and injunctive relief for infringement of any of the Transferred Patents, Subsequent Patents or Know-How Patents.

4.2. Further Actions to Effectuate Transfer. Sobi shall at IPC's request and expense promptly execute and sign any further instruments, applications or documents and take any further actions necessary or useful for IPC (a) to become the registered owner of the Patent Rights; and (b) to otherwise enjoy the full benefit of Patent Rights. Without prejudice to the foregoing, the Parties shall, where appropriate and at IPC's request and expense, execute a separate confirmatory patent assignment document substantially in the form set forth in Schedule 3 ("Confirmatory Patent Assignment"). For the purposes of clarity, the Parties acknowledge that this Agreement is effective as a present assignment of all rights, title, and interest in and to the Transferred Patents and any Subsequent Patents and inventions underlying any future Know-How Patents, but that, one or more Confirmatory Patent Assignments may be executed, to the extent desired or necessary, for example to serve as a recordable instrument documenting such present assignment, or to add any additional rights not deemed to have been assigned by this Agreement. The Parties further agree that IPC shall submit to the relevant patent authorities in the relevant jurisdictions any executed Confirmatory Patent Assignment, amended as reasonably necessary, and shall bear the costs associated with the registration thereof.

4.3. Filing, Prosecution, Maintenance of Transferred Patents. For the avoidance of doubt, and subject to anything to the contrary in the Affibody Agreement, IPC shall as from the Effective Date have the sole right, but not the obligation, at its sole discretion and expense, through counsel of its choosing, to prepare, file, obtain, prosecute (including any interferences, reissue proceedings and re-examinations) maintain, defend and discontinue all Patent Rights throughout the world. Should IPC elect to continue with patent counsel that is currently prosecuting the Transferred Patents, and to the extent required by law or by any applicable rules of professional conduct, Sobi shall, at IPC's request, execute any document that may be required to allow IPC to use such counsel, including any waivers of conflict of interest. During the transition of the Transferred

Patents from Sobi to IPC and until the transfer is complete, Sobi shall at IPC's direction and expense continue to prosecute open applications, and shall file new continuation and/or divisional applications, if and where necessary to seek to ensure that there is no closure of any priority chain in the Transferred Patents and no loss of right to claim priority to any of the Transferred Patents, except as otherwise directed by IPC in writing.

4.4. Enforcement of Transferred Patents. For the avoidance of doubt, as between the Parties, IPC shall as from the Effective Date have the sole right, but not the obligation, at its sole discretion and expense, to enforce the Patent Rights. After the Effective Date, if Sobi has knowledge of any suspected infringement of any Patent Rights, Sobi shall promptly inform IPC of such infringement.

4.5. Cooperation. After the Effective Date and for a period of six (6) months, Sobi shall cooperate with and use reasonable efforts to assist IPC to the extent requested by IPC, including access to and cooperation of relevant Sobi personnel, including inventors, in order to assist IPC to (a) understand the Know How and other Assets; (b) prepare and file new patent applications relating to the Know How (i.e. any Know-How Patents); (c) prosecute and maintain the Patent Rights, including signing inventor declarations and confirmatory or future patent assignments; (d) comply with ongoing patent office disclosure obligations; (e) defend against claims of infringement of third party intellectual property rights; and (f) take action against any third party with respect to actual or suspected infringement or misappropriation of the Patent Rights or other Asset. During the said six month period, Sobi shall cooperate with IPC and supply assistance reasonably requested by IPC. After said six month period, Sobi shall use good faith efforts to facilitate requests by IPC related to items (c) through (f). Upon IPC's request

and at IPC's expense, Sobi shall join IPC as a named party in any such above- referenced proceeding, including providing IPC with such witnesses, documents, assignments and records and other evidence as may be reasonably requested and that is readily available to Sobi.

4.6. Covenant Not to Sue. Sobi shall not, and shall procure that its Affiliates shall not, anywhere in the world, institute or prosecute (or in any way aid any Third Party in instituting or prosecuting) any claim, demand, action or cause of action for damages, costs, expenses or compensation, or for an enjoinment, injunction, or any other remedy, against IPC or its Affiliates alleging the infringement of any Patent or other intellectual property Controlled by Sobi or its Affiliates as of the Effective Date by IPC or its Affiliates due to IPC's or its Affiliates' Exploitation of any Compound, Product or exercise of the Patent Rights.

4.7. Licensees. For the avoidance of doubt and subject to limitations undertaken in the Affibody Agreement, IPC shall have the right to grant to its Affiliates and to any other Person licences, through multiple tiers of licensees, under its rights to any Patent Rights, Product, Compound or any other Asset. Where IPC grants a license under its rights to a Product to a Person, which is not an Affiliate of IPC, and such Person is not a Distributor, that Person shall be a "Licensee" for purposes of this Agreement. IPC shall ensure that all Licensees comply with the royalty payment obligations provided in Section 7.4 and report their Net Sales to IPC such that IPC can comply with its obligations pursuant to Section 7.8. Moreover IPC shall ensure that all Licensees agrees to comply with record retention obligations and accepts and cooperates with any auditing of their records and books as set forth in Section 7.10.

4.8. Distributors. For the avoidance of doubt, IPC shall have the right, in its sole discretion, to appoint its Affiliates – and IPC and its Affiliates shall have the right, in their sole discretion, to appoint any other Persons – to distribute, market and sell the Products, with or without packaging rights. In circumstances where the Person so appointed (i) purchases Products from IPC or its Affiliates but does not otherwise make any royalty or other payment to IPC with respect to its intellectual property rights and (ii) such Person is not an Affiliate of IPC, that Person shall be a "Distributor" for purposes of this Agreement. The term "packaging rights" in this Section 4.8 shall mean the right for the Distributor to package Products supplied in unpackaged bulk form into individual ready-for-sale packs.

5. **Diligent Efforts; Information Sharing**

5.1. General Diligence Efforts. IPC undertakes to use Commercially Reasonable Efforts to successfully research, develop and Exploit at least one Compound Product in the US, EU and Japan.

5.2. Information Sharing. Subject to Section 8.1, within 45 days after each Calendar Year, IPC shall provide Sobi with a written report summarizing key developments in the Program and any planned regulatory filings. IPC shall not be required to provide such reports after the first commercial sale of a Product or during any period that the Non-Compete provisions in Section 8 do not apply.

6. **Third Party Contracts**

6.1. Sobi warrants to the best of its Knowledge that, except for the contracts specified in Schedule 4 (collectively, the "Third Party Contracts"), neither Sobi, nor any of its Affiliates has on or prior to the Effective Date, entered into any contract, agreement, obligation or other arrangement of material importance to the Assets or the Program.

Sobi further warrants that, to the best of its Knowledge, all Third Party Contracts have been complied with in all substantial respects. IPC acknowledges that Sobi has entered into various agreements with Third Party vendors and service providers in relation to the Program, agreements that have expired but under which there may be surviving obligations e.g. regarding confidentiality. The Parties agree that no such contracts shall be assigned to IPC hereunder.

6.2. The Parties agree to take the following actions with regard to the Third Party Contracts:

(a) The [***] and the [***]: In connection with the execution of this Agreement the Parties shall sign notices to the [***] of [***] and [***] in accordance with Schedules 5 and 6 (the "MTA Notices"), which documents Sobi promptly thereafter will send to the respective [***] requesting confirmation of receipt;

(b) The [***] and Affibody PLA: In connection with the execution of this Agreement the Parties will [***] in accordance with Schedule 7, which documents Sobi promptly thereafter will send to Affibody for execution and return of fully executed copies to Sobi and IPC;

(c) The [***] Letter Agreement: Sobi hereby grants IPC an exclusive sublicense under the rights granted to Sobi in the [***] Letter Agreement. The said sublicense is limited to use within the Field and subject to any terms and conditions applicable to Sobi under the [***] Letter Agreement.

(d) The [***] Letter Agreement: Sobi hereby assigns to IPC the [***] Letter Agreement.

(e) The [***] MTA: Sobi hereby grants IPC an exclusive sublicense under the rights granted to Sobi under the [***] MTA for use within the Field and subject to any terms and conditions applicable to Sobi under the [***] MTA, as amended.

(f) The [***] Agreement: While the [***] Agreement will not be assigned, the Parties will endeavour to make arrangements that secure rights for IPC to have the exclusive right in relation to Sobi to use as much as reasonably possible of the [***] Results in the Field and a continued engagement in [***]. For this purpose the Parties have identified the three alternatives set out below. In each of these Sobi shall, subject to what is permissible under the [***] Agreement and any ancillary agreements amongst the [***] Agreement parties, assign or grant a perpetual, irrevocable, fully-paid up and royalty-free sublicense to IPC (with a right to further sublicense) any [***] Results for use in the Field. Sobi shall be entitled to retain ownership to any [***] Results with potential application also outside of Field but shall, subject to the above said limitations, transfer and assign to IPC any [***] Results developed for use only in the Field (e.g. certain molecules). Any sublicense granted to the [***] Results shall be limited to use within the Field and subject to any terms and conditions applicable to Sobi under the [***] Agreement or any ancillary agreements.

- **Alternative A**: Subject to being approved to accede to the [***] Agreement as a new party, IPC shall enter into the [***] Agreement as an independent party and in connection therewith take over and relieve Sobi of its remaining responsibilities in [***]. IPC acknowledges that Sobi will remain a party to the [***] Agreement and that Sobi may either withdraw entirely from [***] or remain as an active participant in [***] but with a different, non C5 related, undertaking. Sobi's undertakings in other program areas under the [***] Agreement are not affected.

- **Alternative B**: If not approved to accede to the [***] Agreement as a new party, IPC shall seek to engage Affibody, on IPC's behalf, to take over and relieve Sobi of its remaining responsibilities under [***]. What is stated in Alternative A regarding Sobi's continued engagement under the [***] Agreement applies correspondingly in Alternative B.

- **Alternative C**: If Alternative A and B are unattainable, IPC shall seek to engage Sobi, on IPC's behalf, to perform Sobi's remaining responsibilities in [***] in return for compensation to be agreed in good faith by the Parties.

If none of Alternative A, B or C are attainable, Sobi may at its sole discretion withdraw from its current responsibilities in [***] without substitution but shall use reasonable efforts to ensure that IPC has rights to the [***] Results as set forth above.

(g) The [***] Agreement: While the [***] Agreement will not be assigned, the Parties will endeavour to make arrangements that secure rights for IPC to use as much as reasonably possible of the [***] Results in the Field. For this purpose Sobi hereby, subject to what is permissible under the [***] Agreement and any ancillary agreements amongst the parties to the [***] Agreement, grant to IPC a perpetual, irrevocable, fully-paid up and royalty-free sublicense to IPC (with the ability to further sublicense) any [***] Results. Any such sublicense shall be limited to use within the Field and subject to any terms and conditions applicable to Sobi under the [***] Agreement or any ancillary agreements. IPC hereby grants Sobi the right and license to continue to use [***] as a reference compound under the [***] Agreement and make it available to the parties of the [***] Agreement as Sobi's Background Information (as defined in the [***] Agreement) during the full term of the [***] Agreement, as it may subsequently be extended.

Nothing in this Agreement shall be construed as an assignment of or grant under a Third Party Contract if such assignment or grant would constitute a breach of such contract.

6.3. Insofar as Affibody does not give its consent to the assignment of the Affibody PLA:

(a) Sobi shall use all reasonable endeavours with the co-operation of IPC to procure such assignment;

(b) unless and until the Affibody PLA has been assigned , Sobi shall continue as party to the Affibody PLA and shall hold any monies, goods or other benefits received thereunder as trustee for IPC;

(c) IPC shall at its own cost, as Sobi's sub-contractor, perform all the obligations of Sobi under the Affibody PLA; and

(d) unless and until the Affibody PLA is assigned, Sobi shall (so far as it lawfully may) give all such assistance as IPC may reasonably require to enable IPC to enjoy and enforce its rights under the Affibody PLA, including, where permissible under the Affibody PLA, terminating Affibody PLA upon IPC's written request, and (without limitation) shall provide access to all relevant books, documents and other information in relation to the Affibody PLA as IPC may require from time to time.

6.4. IPC shall assume all of Sobi's obligations arising after the Effective Date under any Third Party Contract assigned or novated pursuant to this Article 6 and shall, upon any such assignment or novation, be deemed to be a party to such Third Party Contract as though named therein in substitution for Sobi, whereupon Sobi shall cease to be a party to such contract and shall cease to have any rights or obligations thereunder except for any obligations of Sobi that arose on or prior to the Effective Date.

7. **Consideration**

7.1. Total Obligation. The up-front and milestone payments and the royalty payments payable by IPC to Sobi pursuant to this Section 7 represent all of IPC's financial obligations to Sobi hereunder and Sobi shall not be entitled to any additional compensation or remuneration from IPC under this Agreement except as specifically stated herein.

7.2. Up-front and Milestone Payments. In consideration of the Assets sold and other rights granted to IPC by Sobi hereunder and subject to the terms and conditions of this Agreement, IPC shall make the following payments to Sobi:

7.2.1. an aggregate up-front payment of US$ five million (5,000,000), payable in three instalments as follows: (i) US$ three million (3,000,000) within thirty (30) days after the Effective Date, (ii) US$ one million (1,000,000) within eighteen (18) months after the Effective Date, and (iii) US$ one million (1,000,000) within twenty-four (24) months after the Effective Date;

7.2.2. a payment of US$ [***] within [***] days after the [***];

7.2.3. a payment of US$ [***] within [***] days after the [***];

7.2.4. a payment of US$ [***] within [***] days after [***];

7.2.5. a payment of US$ [***] within [***] days after [***];

7.2.6. a payment of US$ [***] within [***] days after [***];

7.2.7. a payment of US$ [***] within [***] days after [***];

7.2.8. a payment of US$ [***] within [***] days after [***];

7.2.9. a payment of US$ [***] within [***] days after [***];

7.2.10. a payment of US$ [***] within [***] days after [***];

7.2.11. a payment of US$ [***] within [***] days after [***];

7.2.12. a payment of US$ [***] within [***] days after [***];

7.2.13. a payment of US$ [***] within [***] days of the end of the Calendar Year in which occurs the first occasion when the Annual Net Sales exceeds US$[***];

7.2.14. a payment of US$ [***] within [***] days of the end of the Calendar Year in which occurs the first occasion when the Annual Net Sales exceeds US$ [***];

7.2.15. a payment of US$ [***] within [***] days of the end of the Calendar Year in which occurs the first occasion when the Annual Net Sales exceeds US$ [***];

7.2.16. a payment of US$ [***] within [***] days of the end of the Calendar Year in which occurs the first occasion when the Annual Net Sales exceeds US$ [***].

For the avoidance of doubt, no payment as per the above provisions in this Section 7.2 shall be made more than once irrespective of the number of Products (or, in respect of the payment set forth in Section 7.2.2 through 7.2.12, Compound Products) that have achieved the milestone events set forth above in this Section 7.2, or the number of countries in which such milestone events have been achieved. The payments as per the above provisions in this Section 7.2 do not include any payments due to Affibody under the Affibody Agreement, which will be paid separately by IPC directly to Affibody.

IPC shall notify Sobi in writing of the achievement of a milestone event set forth above in Section 7.2.2 through Section 7.2.12 within five (5) business days of achievement. IPC shall notify Sobi in writing of the achievement of a milestone event set forth above in Section 7.2.13 through Section 7.2.16 within forty-five (45) business days after the end of the Calendar Year in which the milestone event occurred.

7.3. **Invoices**. Sobi shall send an invoice to IPC in respect of any amounts payable pursuant to Section 7.2 (and in respect of the payment referred to in Section 7.2.1, such invoice shall be submitted to IPC promptly upon the Effective Date).

Each such invoice shall specify (a) the relevant amount invoiced, currency and the milestone event to which such amount is attributable, (b) reference to this Agreement, (c) the number and date of invoice, (d) the latest date of payment (as above stated), (e) name and address of Sobi, (f) bank details, i.e. account number and bank code, and (g) SWIFT-address.

7.4. **Royalty**. IPC shall, subject to Section 7.5, pay royalties to Sobi as follows:

(i) [***] of the Annual Net Sales for that portion of the aggregate Net Sales during the relevant Calendar Year that are less than US$ [***];

(ii) [***] of the Annual Net Sales for that portion of the aggregate Net Sales during the relevant Calendar Year that equal or exceed US$ but does not exceed US$ [***]; and

(iii) [***] of the Annual Net Sales for that portion of the aggregate Net Sales during the relevant Calendar Year that exceed US$ [***].

In the event Annual Net Sales for a period is a negative amount, such negative amount will be carried forward and offset against future Annual Net Sales calculations.

For purpose of clarity, the royalty payments as per this Section 7.4 do not include any payments due to Affibody under the Affibody Agreement, which will be paid separately by IPC directly to Affibody.

7.5. Royalty Term. IPC's obligation to pay royalties shall commence, on a country-by-country basis, with respect to each separate Product, on the date of First Commercial Sale of such Product in such country and shall expire, on a country-by-country basis, with respect to each Product, on the later to occur of (a) the 10th anniversary of the First Commercial Sale of such Product in such country, and (b) the expiration date in such country of the last to expire of any issued Patent included in the Patent Rights that includes at least one Valid Claim covering the sale of such Product in such country. Upon termination of the royalty obligations of IPC under this Section 7.5 with respect to a Product in a particular country, the Net Sales of such Product in such country shall be excluded from the royalty calculations under this Agreement (including the thresholds and ceilings set forth in Section 7.4).

7.6. Sales Subject to Royalties. Sales between IPC, its Affiliates and Licensees shall not be subject to royalties hereunder. Royalties shall be calculated on IPC's, its Affiliates' and Licensee's sale of Products to a Third Party (including Distributors). Royalties shall be payable only once for any given batch of Products. For purposes of determining Net Sales, no royalties shall be payable on transfers by IPC or its Affiliates or Licensees of free samples of Products, clinical trial materials containing Compound, or transfers or dispositions for charitable, promotional, pre-clinical, clinical, manufacturing, testing or qualification, regulatory or governmental purposes.

7.7. Royalty Payments. The royalties payable hereunder shall be calculated annually as of the last day of December for the Calendar Year ending on that date. Within forty-five (45) days after the end of each Calendar Year in respect of which, IPC shall pay any royalties due and deliver to Sobi a written royalty report setting forth, with respect to each country

and each Product, the Net Sales of the Products during such Calendar Year and the royalties due for such Calendar Year. If IPC identifies a correction to a previously made royalty payment was due in respect of a certain Calendar Year, IPC shall adjust any subsequent payment of royalties accordingly. Any such adjustment and the basis for such adjustment shall be clearly specified in the royalty report issued by IPC for the subsequent Calendar Year.

7.8. Compulsory Licenses. If IPC is required to grant a compulsory license to a Third Party as required by the applicable laws of any country under the Patent Rights, and the royalty rate payable to IPC for sales of Product by such Third Party is lower than the royalty rate payable by IPC to Sobi for such sales, then the royalty rate payable hereunder by IPC for sales of Product by such Third Party in such country shall be no greater than the rate payable by such Third Party to IPC for such country, provided IPC receives no other form of compensation or consideration in respect of such compulsory license.

7.9. Third Party Royalty Obligations. If (a) in order to avoid infringement of any patent not licensed hereunder, IPC reasonably determines that it is necessary to obtain a license from a Third Party in order to develop, make, use, sell, offer for sale, supply, cause to be supplied, or import a Product in a country and to pay a royalty or other consideration under such license (including in connection with the settlement of a patent infringement claim), or (b) IPC shall be subject to a court or other similar binding order or ruling requiring any payments, including the payment of a royalty to a Third Party patent holder in respect of sales of any Product in a country then the amount of IPC's royalty payments with respect to Net Sales for such Product in such country shall be reduced by the amounts payable to such Third Party, provided however, that such reduction shall not exceed fifty (50) percent of the royalty otherwise owed to Sobi hereunder referable to the Product sale in question in such country.

7.10. Records Retention; Audit.

7.10.1. IPC shall keep or cause to be kept accurate records or books of account in accordance with applicable generally accepted accounting principles showing the information that is necessary for the accurate determination of the royalties due hereunder with respect to the sale of such Product. IPC shall maintain such records for a period of at least two (2) years after the end of the period for which they were generated or longer if required by law or regulation.

7.10.2. Upon the written request of Sobi, IPC shall permit a qualified accountant or a person possessing similar professional status and associated with an independent accounting firm chosen by Sobi and reasonably acceptable to IPC to inspect during regular business hours all or any part of IPC's records and books necessary to check the accuracy of the royalties paid. The accounting firm shall enter into appropriate obligations with IPC to treat all information it receives during its inspection in confidence. The accounting firm shall disclose to Sobi and IPC only whether the royalty reports are correct and details concerning any discrepancies, but no other information shall be disclosed to Sobi. To the extent not disputed by IPC, any royalties owed and due pursuant to this Agreement as disclosed by the accounting firm and not previously paid by IPC, shall be invoiced by Sobi (in accordance with the invoicing requirements set forth in Section 7.8) and be paid by IPC within thirty (30) days after IPC's receipt of the invoice. Sobi shall pay the charges of the accounting firm, except that if the royalties have been understated by more than [***], the charges shall be paid by IPC. Any overpayments shall be refunded by Sobi to IPC within thirty (30) days of receipt of the auditor's report.

7.11. Late Payments. If IPC at any time should fail to make a Payment to Sobi more than ten (10) business days after the due date specified in this Agreement, Sobi shall be entitled to claim interest on the sum overdue until payment is made, based on the current reference interest rate of the Swedish Central Bank (Sw: Riksbankens referensränta) plus two (2) percentage units, per annum.

7.12. Mode of Payment. All payments set forth in this Section 7 shall be remitted by wire transfer to a bank account of Sobi designated in writing to IPC.

7.13. Currency. All payments required under this Section 7 shall be made in US dollars (US$). For the purpose of computing the royalties payable under Section 7.4 Net Sales of Products sold in a currency other than US$, such currency shall be converted from local currency to US$ by IPC on a monthly basis using the exchange rate published at Oanda.com at the average bid rate on the last day of the month in question.

7.14. Taxes.

7.14.1. General. The royalties, milestones and other amounts payable by IPC to Sobi pursuant to this Agreement ("Payments") shall not be reduced on account of any taxes unless required by applicable laws. Sobi alone shall be responsible for paying any and all taxes (other than withholding taxes required by applicable laws to be paid by IPC) levied on account of, or measured in whole or in part by reference to, any Payments it receives. IPC shall deduct or withhold from the Payments any taxes that it is required by applicable laws to deduct or withhold on

Sobi's behalf. Notwithstanding the foregoing, if Sobi is entitled under any applicable tax treaty to a refund, reduction of rate, or the elimination of, applicable withholding tax, it may deliver to IPC or the appropriate governmental authority (with the assistance of IPC to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to obtain such refund or to reduce the applicable rate of withholding or to relieve IPC of its obligation to withhold tax, and IPC shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, provided that IPC has received evidence, in a form reasonably satisfactory to IPC, of Sobi's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, IPC withholds any amount, it shall pay to Sobi the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to Sobi proof of such payment within thirty (30) days following that payment.

7.14.2. Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, the remitting Party shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an invoice in the appropriate form issued by the receiving Party in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.

8. [***]

8.1. Subject to this Section 8.1 and Section 8.4, Sobi undertakes to IPC that [***], provided, however, that notwithstanding the above in this Section 8.1 [***]; provided, however, that in the event of [***].

8.2. The Parties acknowledge and agree that any [***] in Section 8.1.

8.3. The Parties agree that the [***] in Section 8.1 are [***] under Section 8.1.

8.4. In the event that during the [***], Sobi, its Affiliates or their respective assets is acquired by, or if Sobi or its Affiliates acquires or merges with, a Third Party [***], then: (a) the covenant set forth in Section 8.1 shall not apply to [***]; and (b) [***].

9. **Asset Divestment or Termination of Further Development by IPC**

9.1. If IPC and/or its Affiliates, prior to launch on the US market of the first Compound Product, should decide to divest its rights in the Assets through sale or otherwise, or to terminate all further research, development and commercialisation activities in respect of all Compounds, then IPC shall without unreasonable delay (such notice shall occur within five (5) business days of IPC's decision to divest its rights in the Assets) notify Sobi thereof in writing and grant Sobi a non-exclusive right of negotiation during a period of forty-five (45) days from such written notice (the "Discussion Period"). During the Discussion Period the Parties shall negotiate in good faith with the aim to agree on terms for such a possible business transaction between the Parties relating to the Assets. Sobi's rights under this Section 9.1 shall not apply to (i) a sale of the Assets as part of a transaction to sell substantially all of the assets of IPC and IPC's Affiliates; (ii) a pledge of the Assets as collateral; or (iii) a sale or transfer of the Assets to an Affiliate of IPC, provided that IPC's obligations under this Section 9.1 shall apply to such IPC Affiliate. For the avoidance of doubt, Sobi shall not be obliged to conduct any such negotiations and each Party shall be free to reject any proposal for a possible business transaction submitted by the other Party without having to provide an explanation for such rejection. If the Parties are unable to reach an agreement during the Discussion Period, IPC and/or its Affiliates shall be free to offer the Assets to Third Parties.

10. **[deleted]**

11. **Warranties**

11.1. Each Party warrants to the other (i) that it has full power and authority to enter into this Agreement and has taken all necessary action on its part required to authorise the execution and delivery of this Agreement and (ii) that the execution, delivery and performance of this Agreement will not result in a violation of, or be in material conflict with, or constitute a material default under, any agreement in existence as of the Effective Date or subsequently entered into between it and any other Person.

11.2. Sobi warrants that:

(i) except as set forth in Section 11.3 (ii), to its Knowledge, it has received no notice of any claims, suits, administrative, arbitration or other legal proceedings (including but not limited to patent, tax or employment matters) relating to the Assets or the Program; and

(ii) to its Knowledge, Sobi has disclosed to IPC any information which Sobi reasonably believes would influence a reasonable purchaser's decision to acquire the Assets.

(iii) Sobi owns all right, title and interest in and to the Assets, free of Encumbrances.

(iv) To its Knowledge, Sobi and its subcontractors have complied with all applicable laws, rules and regulations in the research and development of the Compounds and have made no untrue statement of material fact to any regulatory authority, or failed to disclose a material fact to such regulatory authority, with respect to the Assets.

(v) Subject to Section 11.3, and except for the disclosure set forth in Section 11.3 (ii), to its Knowledge: (A) none of the Transferred Patents contain any claim that is invalid or unenforceable, or that has been infringed; (B) the entire contents of the Transferred Patents, including the experimental data, amino acid sequences and sequence listings therein are complete and accurate; (C) Sobi complied with all applicable laws, rules and other requirements in connection with the filing and examination of the Transferred Patents, including without limitation the duty to disclose information material to patentability to the United States Patent & Trademark Office imposed under 37 CFR 1.56; (D) none of the intellectual property or know-how introduced into the Program infringes or misappropriates any Third Party patents, know-how or other intellectual property; (E) neither IPC's practice of the inventions described or claimed in the Transferred Patents, nor the further use, development or commercialization of the Compounds or Compound Products, will infringe any Third Party intellectual property; provided, however, that nothing in this warranty shall be interpreted as a guarantee of non-infringement.

(vi) To its Knowledge, there have been no publications or public disclosures of information contained in unpublished Transferred Patents.

(vii) To its Knowledge, as of the Effective Date, Sobi has not employed any personnel, and has not knowingly used a contractor or consultant, debarred by the FDA (or subject to a similar sanction of a regulatory authority outside the United States), or who is subject of an FDA debarment investigation or proceeding (or similar proceeding of a regulatory authority outside the United States).

11.3. IPC, on its own behalf and on behalf of its Affiliates, agrees and confirms that:

(i) IPC has been given the opportunity to perform a thorough due diligence of the Assets, the Program and the Third Party Contracts prior to entering into this Agreement;

(ii) The Third Party observations received by the [***], have been provided to and shared with IPC;

(iii) Except as explicitly stated in this Agreement, Sobi has made no, and IPC has not relied on any, express or implied, representation or warranty, whether for non-infringement or otherwise, regarding Sobi, the Assets or the Third Party Contracts and no action or omission by Sobi shall be construed as implying any such representation or warranty.

Nothing in this Agreement shall be construed as a warranty or representation by Sobi as to the validity or scope of any of the Transferred Patents or that any of the Patent Rights will be granted, maintained or upheld.

11.4. The transactions contemplated by this Agreement will not result in any employee of Sobi or its Affiliates being entitled to employment by or any payment or other compensation from IPC or its Affiliates.

12. **Indemnification**

12.1. Sobi shall indemnify, defend and hold harmless IPC and its Affiliates from and against any and all Loss (including reasonable expenses of investigation and reasonable attorney's fees and interest when applicable) that may arise as a result of or in connection with (i) Sobi's or its Affiliates breach of any of its warranties, or failure to comply with the provisions set out in this Agreement, (ii) the negligence or wilful misconduct by Sobi or its Affiliates or their respective officers, directors, employees, agents or consultants;

(iii) Sobi's or its Affiliates' use of the Assets prior to the Effective Date; (iv) any claims made or suits brought by any other Person against IPC, its Affiliates or its or their respective directors, officers or employees that allege that the claimant has suffered personal injury or death as a result of use of the Assets prior to the Effective Date. Except as regards any Loss caused by Sobi's gross negligence or wilful misconduct or as set forth in Section 12.1 (iv) above, the aggregate liability of Sobi in respect of claims under this Agreement shall in no event exceed [***] at the time the claim has been finally determined (the "Cap"); provided, however, that the Cap shall not apply to cases of fraud and breaches of Sections 8 (non-compete) and 13 (confidentiality). To the extent that any such Losses exceed the Cap, IPC shall set off and otherwise apply the amount of such Losses against the amounts to be paid by IPC to Sobi pursuant to Sections 7.2.1 through 7.2.12.

12.2. IPC shall indemnify, defend and hold harmless Sobi and its Affiliates from and against any and all Loss (including reasonable expenses of investigation and reasonable attorney's fees and interest when applicable) that may arise as a result of or in connection with (i) IPC's or its Affiliates breach of any of its warranties, or failure to comply with the provisions set out in this Agreement, (ii) the negligence or wilful misconduct by IPC or its Affiliates or their respective officers, directors, employees, agents or consultants; (iii) IPC's or its Affiliates' use of the Assets after the Effective Date; (iv) any claims made or suits brought by any other Person against Sobi, its Affiliates or its or their respective directors, officers or employees that allege that the claimant has suffered personal injury or death as a result of use of the Assets after the Effective Date.

12.3. The indemnifying Party shall not, without the prior written consent of the indemnified Party, agree to a settlement of any claim which could lead to liability or create any financial or other obligation on the part of the indemnified Party for which the indemnified Party is not entitled to indemnification hereunder. The indemnified Party shall cooperate with the indemnifying Party and shall always be entitled to participate in the defense or handling of such claim with its own counsel and at its own expense.

12.4. With the exception of intentional acts or omissions or gross negligence, neither party is liable to the other for any indirect or consequential damages of any kind such as loss of profit, arising out of this Agreement.

12.5. Until the sixth (6th) anniversary of the Effective Date, both Parties agree to maintain at their own cost and expense liability insurance reasonably adequate and customary in the insurance market in relevant locations and jurisdictions. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

13. **Confidentiality**

13.1. For a period of ten (10) years after the date of disclosure each Party (the "Receiving Party") shall, and shall cause its officers, directors and other employees and agents to, keep confidential and not use, publish or otherwise disclose any Confidential Information of the other Party (the "Disclosing Party"); it being agreed that Sobi shall, and shall cause its Affiliates to, treat all Assets, including the Know-How, the Records and the Materials as Confidential Information of IPC, in respect of which Sobi shall, for the purpose of this Article 13, be deemed as the Receiving Party and IPC the Disclosing Party. Notwithstanding the above said, Sobi shall be entitled to retain a copy of such Confidential Information regarding the Assets for the sole purpose of ascertaining its ongoing rights and responsibilities in respect of such information and shall not be required to destroy any computer files stored securely by Sobi or its Affiliates that are (i) created during automatic system back up; or (ii) retained for legal purposes by the legal function of Sobi and its Affiliates.

13.2. The obligations of confidentiality and non-use in Section 13.1 shall not extend to any Confidential Information of the Disclosing Party that:

(i) is or comes into the public domain without breach of this Agreement;

(ii) is received by the Receiving Party from a Third Party without any obligation of confidentiality and without breach of this Agreement; or

(iii) the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party following the Effective Date without use of or reference to any such Confidential Information.

13.3. This Agreement shall not restrict the Receiving Party from complying with a lawfully issued governmental order or legal requirement or the requirements of a national securities exchange or another similar regulatory body to produce or disclose the Disclosing Party's Confidential Information; provided, however, that the Receiving Party shall promptly notify the Disclosing Party of such order or requirement to enable the Disclosing Party to oppose the order or obtain a protective order. If the Receiving Party is thereafter required to disclose such Confidential Information, both Parties will endeavour to agree to a mutually satisfactory means to disclose such information.

14. **Announcements and Use of Name**

14.1. All press releases, public announcements or public relations activities by the Parties with regard to this Agreement or the transactions contemplated by it shall be mutually approved by the Parties in writing in advance of such release, announcement or activity.

14.2. Neither Party shall use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any publication, press release, promotional material or other form of publicity without the prior written consent of the other Party (which shall not be unreasonably withheld), except (i) to the extent necessary for the fulfilment of a Party's obligations under this Agreement, (ii) for those disclosures for which consent has previously been obtained and (iii) that either Party shall, following the completion of such agreed press releases, public announcements or other public relations activities as are referred to in Section 14.1 above, be entitled to disclose to third parties the information contained within any such agreed press release or public announcement or used in any such agreed public relations activities. The restrictions imposed by this Section 14 shall not prohibit either Party from making any disclosure that is required by applicable law, rule or regulation or the requirements of a national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by Section 13.3.

15. **Force Majeure**

15.1. In this Agreement, "Force Majeure" means an event which is beyond a Party's (the "Force Majeure Party") reasonable control, including an act of God, strike, lock-out or other industrial/labour disputes involving the workforce of the Force Majeure Party, war, riot, civil commotion, terrorist act, malicious damage, epidemic, quarantine, fire, flood, storm, natural disaster or compliance with any mandatory law, regulation or governmental order entering into effect following the Effective Date without such law, regulation or order having been reasonably possible to foresee by the non-performing Party prior to the Effective Date.

15.2. The Force Majeure Party shall, within thirty (30) days of the occurrence of a Force Majeure event, give notice in writing to the other Party specifying the nature and extent of the event of Force Majeure, its anticipated duration and any action being taken to avoid or minimize its effect. Subject to providing such notice, the Force Majeure Party shall not be liable for delay in performance or for non-performance of its obligations under this Agreement, in whole or in part, where non-performance or delay in performance has resulted from an event of Force Majeure. The suspension of performance allowed hereunder shall be of no greater scope and no longer duration than is reasonably required.

15.3. The Force Majeure Party shall use reasonable endeavours to (a) bring the Force Majeure event to a close or (b) find a solution by which the Agreement may be performed despite the continuation of the event of Force Majeure.

16. **Governing Law**

The interpretation and construction of this Agreement shall be governed by the laws of England and Wales excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

17. **Disputes**

Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof, shall be finally settled by arbitration in accordance with the Arbitration Rules of the of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The seat of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English.

18. **Notices**

Any notice, request, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement, and shall be deemed given only if hand delivered or sent by an internationally recognised overnight delivery service, costs prepaid, or by fax (with transmission confirmed), to the Party to whom notice is to be given at the following address (or at such other address such Party may have provided to the other Party in accordance with this Section 18):

If to Sobi:

Address:	Swedish Orphan Biovitrum AB (Publ) S-112 76 Stockholm, Sweden
For the attention of:	Chief Executive Officer
With a copy to:	General Counsel
Address:	as per above

If to IPC:

Address:	IPC Research, LLC c/o Grimes & Yvon LLP 800 Third Ave., 28th Floor New York, NY 10022
For the attention of:	Chief Executive Officer

19. **Severability**

If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the Parties. To the fullest extent permitted by applicable law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

20. **Entire Agreement**

This Agreement, the Contract Assignment Agreements, any MTA Notice(s) and any Confirmatory Patent Assignment(s) constitute the entire agreement between the Parties with respect to the subject matter of this Agreement.

This Agreement, the Contract Assignment Agreements, any MTA Notice(s) and any Confirmatory Patent Assignment(s) supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement, the Contract Assignment Agreement, any MTA Notice(s) and any Confirmatory Patent Assignment(s). Nothing in this Agreement, the Contract Assignment Agreements, any MTA Notice(s) and any Confirmatory Patent Assignment(s) is intended to limit or exclude any liability for fraud. All Schedules referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Schedules on one hand and this Agreement on the other hand, the terms of this Agreement shall govern.

21. **Waiver and Non-Exclusion of Remedies**

A Party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by law or otherwise available, except as expressly set forth herein.

22. **Assignment**

Neither Party may assign its rights or delegate its obligations under this Agreement in whole or in part without the prior written consent of the other Party, which shall not be unreasonably withheld; provided, however, that either Party may, without such consent, assign this Agreement (i) to a third party in connection with the transfer or sale of all or substantially all of the assets to which this Agreement pertains or in the event of the merger or consolidation with another entity; or (ii) to an Affiliate. Sobi shall always have the right to assign its right to receive Payments to any of its Affiliates or any Third Party, effective upon written notice of such assignment to IPC.

Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 22 shall be void.

23. **Amendment**

Any amendment or modification of this Agreement must, in order to be valid, be in writing and signed by authorised representatives of both Parties.

24. **Counterparts**

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile transmission or by e-mail of a .pdf attachment shall be effective as delivery of a manually executed counterpart of this Agreement, provided, however, that the Parties shall follow up with and exchange originals signed in wet ink for archival purposes.

25. **Further Assurances**

Each Party shall promptly execute and deliver all such documents and do all such things as may reasonably be required for the purpose of giving full effect to the provisions of this Agreement.

26. **Third Party Rights**

Except as expressly provided in this Agreement, no person who is not a Party to this Agreement shall have the right to enforce any term of this Agreement which expressly or by implication confers a benefit on that person without the express prior agreement in writing of the Parties.

[Signature page overleaf]

Execution

THIS AGREEMENT IS EXECUTED by the authorised representatives of the Parties as of the date first written above.

SIGNED for and on behalf of

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

/s/ Henrik Stenquist
Signature

Name:Henrik Stenquist
Title:CFO

/s/ Torbjörn Hallberg
Name:Torbjörn Hallberg
Title:GC

SIGNED for and on behalf of

IPC RESEARCH, LLC

/s/ Jeffrey M. Fryer
Signature

Name:Jeffrey M. Fryer
Title:Chief Financial Officer

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

PRODUCT LICENSE AGREEMENT

This Agreement (the "**Agreement**"), is made and entered into as of 9 March 2012 (the "**Effective Date**") by and between Affibody AB, company registration no. 556665-6913, Gunnar Asplunds Allé 24, SE-171 63 Solna ("**Licensor**"), and Swedish Orphan Biovitrum AB (publ), (previously Biovitrum AB publ) |company registration no. 556038-9321, Tomtebodavagen 23 A, SE-112 76 Stockholm, Sweden ("**Licensee**"); individually a "**Party**", together the "**Parties**".

1. Background Information

1.1 Licensor is a biotechnology company that has developed Affibody® Molecule Technology and the Albumin Binding Technology, and possesses intellectual property and proprietary know-how regarding the selection and use of Affibody® Molecules and Affibody® Libraries as well as intellectual property and proprietary know-how relating to the Albumin Binding Technology.

1.2 Licensee is a company with extensive experience in developing new therapeutics in various fields.

1.3 The Parties have entered into a Research and Option Agreement, effective as of 24 February 2009, as amended on 17 June 2010, 7 December 2011, and 29 December 011 (the "**ROA**")**,** under which Licensor developed certain Affibody® Ligand(s).

1.4 Under the ROA, Licensor transferred to Licensee the ownership rights to those Affibody® Ligand(s) including any corresponding data and intellectual property claiming the Affibody® Ligand(s) *as such* (subject to the parties entering into this Agreement), resulting in Licensee submitting the patent application no. 1250145-8 *(Polypeptides)* claiming such Affibody® Ligand(s) on February 20, 2012.

1.5 The Parties now wish to set the terms for Licensee's ownership of such intellectual property rights.

1.6 On February 10, 2012, Licensee exercised its option under the ROA to enter into this Agreement.

1.7 The Parties have agreed that Licensee will pay royalties under this Agreement to Licensor in consideration of *inter alia* Licensor's transfer of the Affibody® Ligand(s) and the above mentioned patent application to Licensee, as well as for Licensee's rights to use the Licensed Technology. This means that Licensee will also pay royalties on Net Sales of Licensed Products covered by a Valid Claim in *Product Patent(s).*

1.8 Simultaneously with the ROA, Licensor assigned the intellectual property rights and results which would arise from Licensor's development under the ROA to its Affiliate Affibody SPV I AB. Licensor's parent company, Affibody Holding AB, further pledged its shares in Affibody SPV I AB as security for Licensor's obligations towards Licensee pursuant to the ROA. On 9 March 2012, (i) Affibody SPV I AB retransferred (with Licensee's permission) such rights and results to Licensor, and ratified Licensor's transfer to Licensee mentioned in Section 1.4 above, and (ii) Licensee released the above-mentioned pledge.

1.9 In view of the above, the Parties hereby agree as follows.

2. Definitions

2.1 "**Adverse Event**" means any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product and which does not necessarily have, to have a causal relationship with this treatment, an Adverse Event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. The term Adverse Event shall also include lack of efficacy, reports of exposure during pregnancy (male and female) and from breastfeeding, medication errors, reports of overdose, abuse, misuse and reports of transmission of a suspected infections agent.

2.2 "**Affibody® Library(ies)**" means a collection of DNA molecules containing the DNA corresponding to each Affibody® Molecule in the library.

2.3 "**Affibody® Ligand(s)**" means, individually or collectively, (i) the Affibody® Molecule(s) binding to the Target listed in Appendix A; and (ii) any modifications, analogs, components and/or derivatives of such Affibody® Molecules.

2.4 "**Affibody® Molecule Technology**" means intellectual property rights (including the patents and patent applications in Appendix B, and Licensed Know-how) owned or controlled by Licensor at the Effective Date that cover or relate to (i) Affibody® Molecule(s) and/or Affibody® Library(ies), other than the Affibody® Ligand(s) as such, including but not limited to methods for the preparation of Affibody® Ligand(s) and/or Affibody® Molecules, and/or (ii) Improvements thereof in relation to which Licensee has notified Licensor that it wishes to have a license under Section 3.4, *provided* for clarity that this shall not include the Product Technology.

2.5 "**Affibody® Molecules**" means molecules developed through combinatorial protein engineering of a three helical bundle protein, having structural origin in staphylococcal protein A, and derivatives obtained by further amino acid replacements and/or additions and/or truncations, and all derivatives, analogs, modifications and/or components thereof.

2.6 "**Affiliate**" of a Party means any entity (i) in which fifty percent (50%) or more of the voting equity interests are now or hereafter owned or controlled, directly or indirectly, by a Party, (ii) which now or hereafter owns or controls, directly or indirectly, fifty percent (50%) or more of the voting equity interests of a Party, or (iii) in which fifty percent (50%) or more of the voting equity interest are now or hereafter owned or controlled, directly or indirectly by an entity identified in the preceding clause (i) or (ii).

2.7 "**Albumin Binding Domain**"; or "**ABD**" means Affibody' s proprietary albumin-binding domain(s) [***], and derivatives obtained by further amino acid replacements and/or additions and/or truncations, and all derivatives, analogs, modifications and/or components thereof.

2.8 "**Albumin Binding Technology**" means intellectual property rights (including the patents and patent applications in Appendix C, and Licensed Know-how) owned or controlled by Licensor at the Effective Date that cover or relate to the use of ABD and/or albumin binding, including intellectual property rights related to albumin binding to modify stability, solubility, pharmacokinetics and propensity to aggregate or non-specifically interact, and/or (ii) Improvements thereof in relation to which Licensee has notified Licensor that it wishes to have a license under Section 3.4.

2.9 "**Confidential Information**" is defined in Section 13.

2.10 "**End User**" means a person or entity whose use of a Licensed Product results in its destruction, loss of activity, and/or loss of value.

2.11 "**Field**" means human therapeutic use only.

2.12 "**First Commercial Sale**" means the initial transfer by Licensee or its Affiliates (or a Third Party Transferee of any of the foregoing) of a Licensed Product following market authorization for such Licensed Product, to a Third Party other than a Third Party Transferee of Licensee or its Affiliates, for value and not for demonstration, testing or promotional purposes.

2.13 "**Improvement(s)**" means any registered improvement and/or enhancement (i.e. patent application or patents in or relating to the Platform Technology, that is made, conceived or reduced to practice after the Effective Date by or on behalf of Licensor (or its Affiliates) and/or Licensee (or its Affiliates and/or Third Party Transferees), or jointly by them, as the case may be.

2.14 "**IND Filing**" means an investigational new drug application filed with the US Food and Drug Administration (FDA), a clinical trial application filed with the European Medicines Agency (EMA), or any similar application filed with any other regulatory authority body, in conformance with applicable laws and regulations.

2.15 "**Information Sharing Committee**" or "**ISC**" is defined in Section 6.2.

2.16 "**Know-how**" means scientific, technical and other information that is not in the public domain, including proprietary developments, ideas, designs, concepts, techniques, processes, inventions, discoveries, data, material, reports and research results (without regard to whether such information is patentable or copyrightable).

2.17 "**Licensed Know-how**" means Know-how (existing as of the Effective date or thereafter), all to the extent owned or controlled by Licensor.

2.18 "**Licensed Patents**" means the (i) patents and patent applications claiming the Affibody® Molecule Technology set out in Appendix B, (ii) patents and patent applications claiming the Albumin Binding Technology set out in Appendix C, (iii) any and all patents issuing there from and (iv) any and all foreign counterparts, divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, revalidations, reissues, provisional applications of the patents or patent applications listed in (i)-(iii) above. For clarity, any references in this Agreement to "*Licensed Patents listed in Appendix B/C*", as the case may be, shall also include references to the patent(s) and patent application(s) listed in (iii)-(iv) above.

2.19 "**Licensed Product**" means any product that comprises or incorporates one or more Affibody® Ligand(s) alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions).

2.20 "**Licensed Technology**" means the Licensed Patents and the Licensed Know-how.

2.21 "**Losses**" is defined in Section 16.1

2.22 "**Net Sales**" means the amounts received on sales of Licensed Products by Licensee, its Affiliates and any Third Party, Transferee, less any of the following to the extent included in such amounts: [***].

In any transfers of Licensed Products between Licensee and one of its Affiliates or between any of the foregoing and a Third Party Transferee and its Affiliates, the Net Sales shall be calculated based on the final sale of the Licensed Product to parties which are not Affiliates of Licensee or of such Third Party Transferee.

In the event that non-monetary consideration is received for any Licensed Products, Net Sales with respect to such Licensed Products shall be calculated based on the fair market value of such consideration.

Licensed Products supplied by way of sample (free of charge) or for purpose of research and development (against no consideration), including use in any clinical trial carried out by or on behalf of Licensee, its Affiliates, Third Party Transferees or any academic institution under an investigator sponsored clinical study supported by any of the aforementioned, transfers of Licensed Products (against no consideration), to patients under Licensee's, its Affiliates' or any of its Third Party Transferees' patient assistance programme or compassionate use programmes in any country, or other transfers or dispositions (against no consideration), for charitable, promotional, manufacturing, testing or qualification, regulatory or governmental purposes shall not be deemed to be sales, and shall not be included within any Net Sales calculation.

2.23 "**Phase II Clinical Trial**" means studies of a molecule in a limited number of patients to determine efficacy in the indication for which a product is intended, in order to provide proof of concept or to determine optimum efficacious dosing regimens.

2.24 "**Phase III Clinical Trial**" means a controlled and lawful study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file a regulatory submission to obtain regulatory approval by FDA, EMA or any other regulatory authority to market the product, as further defined with respect to the United States of America in Federal Regulation 21 C.F.R. § 312.21(c).

2.25 "**Platform Technology**" means the Affibody® Molecule Technology and/or the Albumin Binding Technology, and any Improvements thereof, *provided* that this shall not include the Product Technology.

2.26 "**Product Technology**" means the Affibody® Ligand(s) as such and any other intellectual property, information know-how, data, materials and reports regarding the Affibody® Ligand(s) , *is such*, alone or as a fusion protein (i.e. ABD-fusion, PEGylated proteins, and/or Fc-fusions), but not the ABD *as such*. For the avoidance of doubt, and without limiting the generality of the foregoing, Licensee will exercise its rights and licenses under this Agreement to develop the Affibody® Ligand(s) into pharmaceutical product(s) and the development activities will result in intellectual property information and Know-how relating to such (investigational) pharmaceutical product, including without limitation, pharmaceutical formulations, manufacturing processes for the pharmaceutical product, pharmaceutical uses, such technology (although owned by Licensee to the extent not considered to be Platform Technology) shall not be considered to be Product Technology.

2.27 "**Product Patent(s)**" means (i) patents(s) or patent application(s) claiming the Affibody® Ligand(s) *as such*, alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions) filed before, on or after the Effective Date (including patent application no. 1250145-8, filed February 20, 2012), (ii) any and all patents issuing there from, and (iii) any and all foreign counterparts, divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, revalidations, reissues, provisional applications of the patents or patent applications listed in (i)-(iii) above. For the avoidance of doubt, and without limiting the generality of the foregoing, Product Patents shall not include patent(s) or patent application(s) that does not claim the sequences per se of any Affibody® Ligand(s) alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions).

2.28 "**Representatives**" is defined in Section 16.1.

2.29 "**ROA**" is defined in Section 1.3 above.

2.30 "**Royalty Term**" is defined in Section 9.5 below.

2.31 "**Target**" means complement factor 5 (C5).

2.32 "**Term**" means the term of this Agreement, which shall commence on the Effective Date and continue until the last Royalty Term to expire, i.e. when Licensee no longer is obliged to pay royalty to Licensor.

2.33 "**Territory**" means all countries in the world.

2.34 "**Third Party Transferee**" means any other party other than an Affiliate of Licensee which is authorized by Licensee or to whom Licensee otherwise grants any right to research develop, make, have made, use, sell and have sold Licensed Products within the Field and the Territory (e.g. sub-licensees, and marketing/co-promotion partners). This notwithstanding, "Third Party Transferee" shall not include a third party that distributes, markets and sells Licensed Products, with or without packaging rights, in circumstances where the person so appointed purchases its requirements of Licensed Products from Licensee or its Affiliates but does not otherwise make any royalty or other payment to Licensee with respect to its intellectual property rights (e.g. physical distributors or whole-sellers). The term "packaging rights" in this Section 2.34 shall mean the right for the distributor to package Licensed Products supplied in packaged bulk form into individual ready-for-sale packs. Further, Licensee's service providers (cf. Section 3.6 below) shall not be deemed Third Party Transferees in each case so long as Licensee is not receiving any consideration or other payments from such third parties in exchange for the sublicense of Licensee's rights.

2.35 "**Third Party**" means any individual or entity other than Licensor or Licensee or their Affiliates.

2.36 "**Valid Claim**" means (a) a claim of an issued and unexpired Licensed Patent and/or Product Patent that has not been disclaimed, permanently revoked, held unenforceable, unpatentable or invalid by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through re-examination, reissue, disclaimer or otherwise, or lost in an interference proceeding brought by a Third Party (without involvement by Licensee or its Affiliates); and (b) a claim of any pending application included in the Licensed Patent(s) and/or Product Patent(s) to the extent the subject matter described in such claim has not been abandoned without being re-filed in another application or finally rejected by an administrative agency action from which no appeal can be taken, or which claim has not been pending for a period of more than seven (7) years (or, in respect of any Japanese application, ten (10) years), from the date of the application. Notwithstanding what is stated above in clause (b), any claim within the Licensed Patent(s) and/or Product Patent(s) that ceases to be a Valid Claim as a result of pending too long or otherwise, but subsequently issues and is otherwise described by clause (a) above shall become a Valid Claim for purposes of this definition, effective as of the issuance of such patent.

3. License Grants

3.1 **License to Swedish Orphan Biovitrum**. Subject to the hereby terms and conditions of this Agreement, Licensor grants to Licensee:

a) a non-exclusive license to the Licensed Patent(s) listed in Appendix B to use the Affibody® Ligand(s) alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions), within the Field;

b) an exclusive right (to the extent that Licensee has not already such rights due to its ownership of the Affibody® Ligand(s)) to use the Affibody® Ligand(s), alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions), within the Field;

c) a non-exclusive license to the Licensed Patents listed in Appendix C, solely to the extent necessary for Licensee to use the ABD in combination with the Affibody® Ligand(s) as a fusion protein, as set forth in d) below;

d) an exclusive right to use the ABD solely in combination with the Affibody® Ligand(s) as a fusion protein, within the Field; and

e) a non-exclusive license to use the Licensed Know-how, solely to the extent necessary for Licensee to practice the rights and licenses set forth in a)—d) above;

in each case a)—e) above, including a right to sublicense in accordance with the terms set out in Section 4, solely to research, develop, make, have made, use, sell and have sold Licensed Products within the Field in the Territory.

For clarity, the non-exclusive licenses in a), c) and e) granted by Licensor above are only intended to allow Licensee and its permitted Third Party Transferees freedom to operate under such Licensed Patents and the Licensed Know-how with respect to their practice of the rights in b) and d) and not for any other purpose.

3.2 **Option to include Improvements to the Platform Technology**. Licensor shall notify Licensee on creating, discovering, acquiring or developing any material Improvement that Licensor deems, in its reasonable discretion, to be commercially reasonable for Licensee to practice, giving details of the same. Licensee shall inform Licensor, within one hundred and twenty (120) days of receiving such notice, whether Licensee wishes to have a license to such Improvement to use the same for the purpose of exploiting its rights under Section 3.1 above.

3.3 Licensee may further at any time request to take a license to any Improvements made by Licensee (or its Affiliates and/or Third Party Transferees) and transferred to Licensor pursuant to Section 11.1).

3.4 If Licensee notifies Licensor that it wishes to take a license to an Improvement, such Improvement shall be deemed to fall within the definition of Affibody® Molecule Technology or Albumin Binding Technology, as the case may be, and the Licensed Patents licensed pursuant to Section 3.1 shall be extended accordingly.

3.5 **License to Affibody**. Licensee hereby grants to Licensor:

a) an exclusive, royalty-free, worldwide, perpetual, irrevocable license (including the right to grant sub-licences) under any Product Patents owned or controlled by Licensee (or its Affiliates and/or Third Party Transferees), to use the Affibody® Ligand(s), outside the Field, and

b) a non-exclusive royalty-free, worldwide, perpetual, irrevocable license (including the right to grant sub-licences) under any Know-how in the Product Technology, which is directly related to the use of Affibody® Ligand(s) as such, to the extent necessary for Licensor to practice the Product Patents outside the Field. For clarity, this non-exclusive license is only intended to allow Licensor and its sub-licenses freedom to operate under the Product Patents outside the Field and not for any other purpose. Licensee will further not be required to perform any technological transfer or "show-how" or similar activities as a consequence of this license.

3.6 **Limitation of Rights**

a) Notwithstanding Licensee's ownership of the Affibody® Ligand(s) *as such*, Licensee may not transfer or otherwise make available any Affibody® Ligand(s) or ABD on a stand-alone basis, i.e. other than as a part of a Licensed Product, except to (i) non-commercial Third Parties for research use, (ii) to Third Parties for testing and evaluation purposes in the Field and (iii) to Third Parties solely for the purpose of developing or making the Affibody® Ligand(s) (alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions)) or Licensed Products *for Licensee* under contract for the purpose of commercializing a Licensed Product.

b) Licensee may further not transfer or otherwise make available the ABD other than in combination with the Affibody® Ligand(s) as a fusion protein, and in that case, only as a part of a Licensed Product as set out in 3.6 a) above.

c) Licensee is expressly prohibited from selling, transferring or otherwise making available to Third Parties Licensed Products, ABD or Affibody® Ligand(s) for use outside the Field.

d) To the extent permitted by applicable law, all product labels for Licensed Products shall restrict the End Users' use to the Field.

4. Sub-licensing

a) Licensee may sublicense its rights pursuant to Section 3.1 to Third Party Transferees; *provided* that such sublicense is consistent with the terms and conditions of this Agreement. The Parties agree that Licensee is not entitled to sub-license the right to use the ABD or the license to the Albumin Binding Technology separately from the right to use the Affibody® Ligand(s). Licensee is, however, entitled to sub-license its rights to research, develop, make, have made, use, sell and have sold Licensed Products, in whole or in part.

b) Sublicenses shall be made non-assignable and non-transferable without the prior written consent of Licensor, not to be unreasonably withheld or delayed.

c) The right to grant further sublicenses (i.e. sub-sub-licenses) is subject to the prior written consent of Licensor, not to be unreasonably withheld or delayed. Licensee remains primarily responsible for, and shall ensure that each Third Party Transferee complies with the terms of this Agreement, including all confidentiality, diligence, payment, audit rights and reporting obligations. Promptly after execution of an agreement with a Third Party Transferee, Licensee will provide Licensor with a copy of each such sublicense agreement, of which Licensee may redact provisions that do not relate to compliance of such sublicense agreement with this Agreement or of Licensee's or its Third Party' Transferee's compliance with the terms and conditions of this Agreement, in addition. Licensee shall cause sublicenses and any permitted sub-sub-licenses to be automatically terminated by termination of this Agreement (for any reason or cause), at which time any Third Party Transferee that is not then in default will be entitled to negotiate, directly with Licensor, a license.

5. Target Exclusivity

Licensor undertakes, for a period of seven (7) years from the Effective Date, not to, for its own behalf or of any Third Party's benefit, commercially exploit or perform any research relating to the Target within the Field.

6. Diligence Efforts; Information Sharing Committee, etc.

6.1 **General Diligence Efforts**. Licensee undertakes to work diligently and agrees to use commercially reasonable efforts consistent conditions to successfully research, develop and otherwise carry out the development and commercialization of a Licensed Product, devoting at least the same level of diligence to such efforts that it devotes to products at a similar stage in its product life cycle and of similar development and market potential, but not less than reasonable diligence.

6.2 **Information Sharing Committee.** The Parties shall establish an information sharing committee (the "**ISC**"), consisting of equal numbers of representatives from each Party. The ISC will serve as a forum for the Parties' information exchange under this Agreement.

a) In particular, the ISC will be responsible for information sharing and discussion between the Parties pursuant to this Agreement regarding: i) material improvements according to Section 11.5b) during the previous six (6) month period, ii) sharing of general and material drug class effects (e.g. drug-drug interactions, PK on a population level, immunogenicity) and material negative findings relating to the Licensed Technology or Product Technology during preclinical and clinical phase, and iii) diligence monitoring (progress of the development, e.g. reporting of program status, achieved results and program timelines, and similar activities relating to the development of Licensed Products pursuant to this Agreement.

b) The ISC shall meet (either in person or by telephone conference) at least once every six (6) month period during the first five (5) years in which development is ongoing.

7. Compliance with Laws

Licensee shall comply, and shall cause all Affiliates and Third Party Transferees to comply, with all laws, regulations, rules, and orders applicable to the testing, production, manufacture, transportation, packaging, labeling, promotion, export, distribution, sale, and use of the Licensed Products.

8. Branding; Trademarks; Adverse Drug Reaction Reporting

8.1 **Branding.** To the extent permitted under applicable laws, Licensee shall state, and shall cause all Affiliates and Third Party Transferees to state, on secondary packaging and product information leaflets of Licensed Products that the Licensed Products are manufactured under a license from Licensor; *provided*, *however*, that the placing and size of such statement shall not be more prominent than Licensee's own branding statement.

8.2 **Trademarks for Licensed Products.** Licensee shall determine the trademark and/or tradename that will be used to market and sell the Licensed Products in the Territory, and any such trademark and tradename shall be and remain the sole and exclusive property of Licensee.

8.3 **Pharmacovigilance.** Within three (3) months of submission of a marketing authorization in the first of the United States or EU, the safety responsible of each Party will develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events relating to Licensed Products, product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, and Third Party Transferees to comply with all its legal obligations, including to the extent applicable, those obligations contained in ICH guidelines E2A, E2B. E2C E2D: Each Party will designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of Adverse Events.

8.4 **Reporting of Serious Findings.** From the Effective Date, Licensee undertakes to notify Licensor promptly of any findings relating to the Licensed Products, which are serious or unexpected and that suggest a risk to humans, including but not limited to, for example, abnormal laboratory findings or findings of mutagenicity, teratogenicity or carcinogenicity.

9. Remuneration

9.1 **License Fee.** Licensee shall pay to Licensor the non-refundable amount of EUR 500,000 upon execution of this Agreement and receipt of an invoice thereof, which shall be due and payable within ten (10) days.

9.2 **Milestone Payments.** Licensee shall pay to Licensor the following non- refundable lump sums, as and when applicable:

Milestone	Milestone Payment*
[***]	EUR [***]
[***]	EUR [***]
[***]	EUR [***]
[***]	EUR [***]
[***]	EUR [***]

* One-time payment; irrespective of the number of Licensed Products that achieve a Milestone, Licensee shall only be obligated to make a Milestone payment once for the first Licensed Product to reach the Milestone. For the avoidance of doubt, if the *first* Licensed Product should reach one Milestone but not the next, then Licensee shall make such Milestone payment due for the *second* Licensed Product to reach this next Milestone. *Example*: The first Licensed Product reaches Milestone [***], but not Milestone [***]. If a second Licensed Product should reach Milestone [***] and Milestone [***], for the second Licensed Product Licensee would pay for [***] (but not for Milestone [***].

9.3 **Payment of Milestone Payments.** Licensee shall pay Milestone Payments upon the event triggering such Milestone Payment and receipt of an invoice thereof, which shall be due and payable within [***] days. Licensee shall without undue delay inform Licensor on the occurrence of the events triggering a Milestone Payment listed in Section 9.2.

9.4 **Royalties**. Licensee shall, during the Royalty Term, pay Licensor royalty payments on Net Sales of Licensed Products as follows: (i) at the rate of [***] if the Licensed Product is covered by a Valid Claim, and (ii) at the rate of [***] if the Licensed Product is not covered by a Valid Claim. Licensee is not obligated to pay multiple royalties if any Licensed Product is covered by more than one Valid Claim within the Licensed Patents.

9.5 **Royalty Term.** Royalties on Net Sales shall be payable on a country-by- country, Licensed Product-by-Licensed Product basis, for the longer of: (i) the last Valid Claim to expire in such country; or (ii) ten (10) years from First Commercial Sale of each such Licensed Product in each country (the **"Royalty Term").** The Parties agree that Licensor's transfer of the Affibody® Ligand(s) and its right, title and interest in the Product Technology to Licensee and the technology licensed to Licensee justify royalties that apply in countries where no Valid Claims exist, and royalties that apply after the expiry of Valid Claims in a country (if the last Valid Claim expires before ten years from First Commercial Sale), and that such payments constitute consideration for Licensor's transfer to Licensee of the Product Technology pursuant to the ROA and this Agreement. Upon expiration of the Royalty Term for a Licensed Product in a country, Licensee shall have a fully-paid-up, irrevocable, royalty-free, nonexclusive, perpetual, worldwide, sub-licensable license as granted to Licensee in Section 3.1, to research, develop, make, have made, use, sell and have sold such Licensed Product within the Field in such country. Licensor further agrees not to sell, transfer or otherwise make available the Affibody® Ligand(s), alone or as a fusion protein (i.e. ABD-fusions, PEGylated proteins, and/or Fc-fusions), in the Field after expiration of the Royalty Term. However, notwithstanding

what is stated above, if the Agreement is terminated by Licensor due to circumstances set out in Sections 18.3-18.5, or by Licensee pursuant to Section 18.2, Licensee shall as from the effective date of termination, no longer have any licenses hereunder nor shall Licensor be bound by its undertaking regarding the Affibody® Ligand(s) set out in this Section 9.5.

9.6 **Royalty Payment Provisions.** Royalties under this Agreement shall be calculated for every calendar quarter and shall be paid in EUR within [***] days from the expiration of the relevant calendar quarter, and shall be deemed to have been made when the money is available in the account designated by Licensor. Whenever for the purpose of calculating royalties conversion from foreign currency shall be required, the rate of exchange shall be the Swedish Central Bank official average conversion rate for the relevant currencies and the relevant calendar quarter.

9.7 **Withholding Taxes.** In the event that Licensee, an Affiliate or a Third Party Transferee is required to withhold any tax to the tax or revenue authorities in any country regarding any royalty due to the laws of such country, such amount shall be deducted from the royalty to be paid by Licensee hereunder, and Licensee shall notify Licensor and promptly furnish Licensor with copies of any tax certificate or other documentation evidencing such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from or collecting such deductions.

9.8 **Late Payments.** If Licensee at any time should fail to make payment in full on the due date, Licensor shall be entitled to claim interest on the sum overdue until payment is made, based on the current reference interest rate of the Swedish Central Bank plus four (4) percentage units, per annum.

9.9 **Invoicing Procedure.** All invoices shall reference this Agreement and be in the format specified in writing by Licensee from time to time.

9.10 **VAT.** All sums payable under this Agreement are exclusive of any value added tax or any other sales tax or duties, which where applicable, shall be payable by the payer in addition to any sum in respect of which they are calculated.

10. Records, Reports and Auditing

10.1 **Records.** Licensee shall maintain, and shall cause its Affiliates and Third Party Transferees to maintain, for a period of three (3) years following the end of the calendar year to which they pertain, full and true books of accounts and other records in sufficient detail so that the royalties and other payments payable to Licensor hereunder can be properly ascertained. These records shall be ready for inspection and examination during normal business hours upon no less than fifteen (15) business days written notice, to an independent auditor, to which Licensee has no objections and who is bound by a confidentiality agreement, for the sole purpose of verifying correct royalty payments. Licensee shall co-operate at such audit, and shall give any explanations that may reasonably be requested. The cost for such audit shall be borne by Licensor. However, and without prejudice to any other remedy or action available due to breach of this

Agreement, if the audit should determine a discrepancy between royalty reported and the royalty actually due resulting in underpayment of royalties of more than [***] or if the audit (of such books, accounts or records) should determine a discrepancy between permitted use under this Agreement and actual use of the Affibody® Ligand(s), ABD or Licensed Technology, then the cost and expense of the audit shall be borne by Licensee. Licensee shall promptly pay to Licensor all amounts determined by any inspection to be due to Licensor, with interest in accordance with Section 9.8 above from the date the same should have been paid.

10.2 **Reports.** Licensee shall at each time of payment of royalties dispatch to Licensor a written report, concerning the computation of royalty and other payments payable by Licensee to Licensor hereunder. Each such report shall contain total number of units of Licensed Products sold or transferred by Licensee, an Affiliate or a Third Party Transferee during the most recent calendar quarter on a Licensed Product-by-Licensed Product, country-by-country basis, together with any exchange rates used for conversion, and total royalties due. Receipt or acceptance by Licensor of any of the reports furnished pursuant to this Section 10.2 or of any sums paid hereunder shall not preclude Licensor from questioning the correctness thereof at any time, and in the event any inconsistencies or mistakes are discovered in such reports or payments, they shall be promptly rectified and appropriate payment, if necessary, shall be made by Licensee of any amounts. Licensor shall grant Licensee credit for any overpayment against the next calendar quarter royalty payment.

11. Ownership of Intellectual Property Rights; Patent Prosecution and Maintenance

11.1 **Platform Technology.** Licensor shall be and remain the sole and exclusive owner of all rights, title and interest on a worldwide basis in and to the Platform Technology (including, for clarity, any Improvements thereof), and, for that purpose, Licensee hereby assigns, and Licensee shall cause its Affiliates, employees, consultants, and agents to assign, its right, title, and interest in and to ail Platform Technology to Licensor.

11.2 **Licensed Patents.** Licensor shall be registered as applicant, holder, or assignee (as the case may be) of any Licensed Patent(s). Licensor shall be responsible, at its expense and discretion, for the preparation, filing, prosecution, maintenance and defense of Licensed Patent(s). This notwithstanding, Licensor agrees that it will not file any new patent applications claiming the Platform Technology that refer to the Affibody® Ligand(s) without Licensee’s prior consent. Licensor shall submit to Licensee any material information regarding any Licensed Patents.

11.3 **Product Technology.** Licensee shall be and remain the sole and exclusive owner of all rights, title and interest on a worldwide basis in and to the Product Technology (including the Product Patents), and, for that purpose, Licensor hereby assigns, and Licensor shall cause its Affiliates, employees, consultants, and agents to assign, its right, title, and interest in and to all Product Technology (including the Product Patents) to Licensee.

11.4 **Product Patents.** Licensee shall be registered as applicant, holder, or assignee (as the case may be) of any Product Patent(s). Licensee shall be responsible, at its expense and discretion, for the preparation, filing, prosecution, maintenance and defense of any Product Patent. Licensor shall cooperate with Licensee in obtaining patent protection for the Affibody® Ligand(s) and/or the Product Technology by furnishing available information and by procuring the signature of necessary documents by its employees.

11.5 **Information to Licensor.**

a) Licensee shall submit to Licensor any material information regarding any Product Patent. Licensee shall (i) invite Licensor to comment on any material issues with regard to scope of protection of the Product Patent in relation thereto well in advance before a relevant deadline and (ii) take into due consideration Licensor's comments and requirements.

b) Where Licensee develops any material improvements to Product Technology which may also be applicable to the Platform Technology, it shall notify Licensor and the Parties shall discuss any appropriate measures to preserve confidentiality and/or appropriate arrangements with regards to the allocation ownership of the Platform Technology and the Product Technology.

11.6 **Subsidiary Rights to Prosecute.** If Licensee elects not to file, or to further pursue prosecution or maintenance of a Product Patent in any country. Licensee shall notify Licensor at least ninety (90) days prior to any relevant deadline. If Licensor so requests, then Licensee shall file, prosecute and maintain any Product Patent in countries not selected by Licensee, at Licensor's expense. Licensor further shall have the right to pursue, at its expense, prosecution, procurement and maintenance of such Product Patent, in Licensee's name but at Licensor's expense,

11.7 **Cooperation.** Each Party shall, at their own expense, provide the other Party with such assistance as the other Party shall reasonably request in connection with any proceedings where the ownership, validity or subsistence of any of the Product Patent is at issue (including opposition proceedings in respect of European patents and nullity and interference proceedings in respect of US patents).

11.8 **No obligation to file.** Nothing in this Agreement shall be construed as an obligation to file, prosecute and maintain any patent applications or issued patent, including the Licensed Patents.

12. Infringements

12.1 **Notice.** Each Party agrees to provide written notice to the other Party promptly after becoming aware of any actual or potential infringement of the Licensed Technology and/or Product Technology (including Product Patent(s)). The Parties agree to keep each other continuously informed of the status of any such infringement. In the event of any such notice of infringement, the Parties shall discuss the most appropriate actions to take.

12.2 **Right to prosecute infringements.** Licensor, to the extent permitted by law, shall have the first right, under its own control and at its own expense, to pursue and prosecute any Third Party infringement of the Licensed Technology. Licensor shall promptly inform Licensee if it elects not to exercise such first right (but in any event within sixty (60) days after notice of such infringement pursuant to Section 12.1), and Licensee shall thereafter, after Licensor's prior written approval not to be unreasonably withheld or delayed, have the right to pursue and prosecute such actions, either in its own name or in the name of both Parties, if necessary. If required by law, each Party shall permit any action under this Section 12.2 to be brought in the other Party's name, *provided* that the Party bringing the action shall reimburse the other Party against, any out of pocket costs or expenses that such Party incurs in connection with such action

12.3 **Right to prosecute infringements; Product Patents**. The provisions in Section 12.2 shall also apply to infringements relating to Products Patents, *except* that Licensee shall have the first right to pursue and prosecute any Third Party infringement, and Licensor will have the subsidiary right to pursue infringements.

12.4 **Recovery.** Any recovery obtained as a result of infringement actions brought under Sections 12.2 or 12,3, whether by judgment, award or settlement, shall be applied in the following order of priority:

(i) First be applied to reimbursement of each Party's out-of-pocket expenses in bringing such suit or proceeding including, but not limited to, court costs and attorney fees.

(ii) Second, any remainder shall be allocated and distributed between the Parties as follows:

a) if the entire recovery or a substantial part thereof, was based upon the effect of the infringement on the development and/or commercialization of Licensed Product(s) in the Field; then the recovery shall be treated as if it were Net Sales during the relevant calendar quarter subject to the applicable terms of this Agreement (i.e., Licensee shall be entitled to all of such recovery less royalties payable to Licensor under Section 9.4);

b) if the entire recovery or a substantial part thereof, was based upon the effect of infringement on the development or commercialization of Affibody® Ligand(s) outside the Field, or on the use of Licensed Technology non-exclusive to Licensee without affecting the development or commercialization of Licensed Product(s), then Licensor shall be entitled to all of such recovery;

c) in any other scenario than as described above, the recovery shall be allocated among the Parties based upon the relative effect of the infringement on the development or commercialization of Licensed Product(s) in the Field, Affibody® Ligand(s) outside the Field, or on the use of the Licensed Technology by both Parties, as determined by the Parties in good faith. Any amounts allocated to Licensee shall be treated as if it were Net Sales during the relevant calendar quarter subject to the applicable terms of this Agreement (i.e., Licensee shall be entitled to all of such recovery less royalties payable to Licensor under Section 9.4).

12.5 **Action initiated by a Third Party.** Licensee, to the extent permitted by law, shall have the first right, under its own control and at its own expense, to control any claim made or threatened against Licensee that Licensee's use of the Licensed Technology infringe any Third Party's intellectual property rights within the Field. No settlement, consent judgment or other voluntary final disposition of any such suit may be entered into without the prior written consent of Licensor, which consent shall not be unreasonably withheld or delayed. Licensee shall promptly inform Licensor if it elects not to control such an action (but in any event within sixty (60) days after notice of such action pursuant to Section 12.1), and Licensor shall thereafter have the right to control any action initiated by a Third Party, either in its own name or in the name of both Parties, if necessary, in which case the principles set forth in Sections 12.2 and 12.4 governing actions in the other Party's name, allocation of costs and recovery shall apply.

12.6 **Cooperation.** Each Party agrees to cooperate in any action under this Section 12 that is controlled by the other Party, *provided* that the prosecuting Party reimburses the other Party promptly for any out-of-pocket costs and expenses incurred by the non-prosecuting Party in connection with providing such assistance.

13. Confidentiality

a) Licensee acknowledges that Licensor will be disclosing to Licensee confidential information regarding the Licensed Technology, and Licensor acknowledges that Licensee will be disclosing to Licensor confidential information regarding Licensee's research, development, manufacturing, sales and marketing activities ("**Confidential Information**"). Such information, whether received in oral, electronic or written form shall be kept in strict confidence, used only for the purposes of this Agreement and not disclosed by the recipient Party to any Third Party other than its employees, directors, advisors or Third Party Transferees, who are under a confidentiality obligation substantially equivalent to that of the receiving Party, without the prior written consent of the other Party. The Parties agree that the material terms of this Agreement will be considered Confidential Information of both Parties.

b) These obligations of confidentiality and non-use shall not apply to Confidential Information that (i) is publicly available by use and/or publication before its receipt from the disclosing Party or an Affiliate of the disclosing Party, or on their behalf, or thereafter become publicly available through no fault of the receiving Party; (ii) was already in the receiving Party's possession prior to receipt from the disclosing Party or an Affiliate of the disclosing Party, or on their behalf, as evidenced by records kept by the receiving Party in the ordinary course of business; or (iii) is properly obtained by the receiving Party from a Third Party who has a valid right to disclose such information to the receiving Party, is not under a confidentiality obligation to the disclosing Party or an Affiliate of the disclosing Party, and is not disclosing such information to the receiving Party on behalf of the disclosing Party or an Affiliate of the disclosing Party.

c) This Section 13 shall not be construed to prohibit disclosure of Confidential Information to the extent that such disclosure is required to by law or valid order of a court or other governmental authority, or by stock market regulations; provided, however, that the responding Party shall first have given notice to the other Party and shall have made a reasonable effort to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued.

d) Nothing contained herein shall prevent a Party from disclosing information to the extent such information is required to be disclosed

e) in connection with securing any necessary governmental authorization for Licensee's manufacture, use or sale of a Licensed Product, (ii) for the purposes of Licensee's compliance with governmental regulations, (iii) for the purposes of development or manufacture of any Licensed Product and (iv) to employ Third Party consultants or enter into collaboration agreements, provided that such Third Party is subject to confidentiality obligations commensurate with those in this Section 13.

f) The Parties further acknowledge that they each may engage in fundraising activities with private investors. In such event, the Parties may disclose the existence of this Agreement, including its terms and subject matter, under terms of confidentiality no less strict than those contained in this Agreement, to such investors or potential investors in or potential licensees of the disclosing Party conducting due diligence in each instance.

g) The disclosing Party shall remain responsible for the unauthorized disclosure by any Affiliates or Third Parties.

h) The Confidentiality undertaking above shall apply during the Term and for seven (7) years thereafter.

14. Use of Names and Trademarks and Publication

14.1 **Use of Names and Trademarks.** Both Parties may use the other Party's name and/or trademarks in external communications. Any such use shall be the subject of the other Party's consent not to be unreasonably withheld or delayed.

14.2 **Publication.** Both Parties may refer to the other Party in external communications or in a press release upon the signing of this Agreement, however may not disclose any financial terms of this Agreement. In addition, Licensor may not disclose the identity of the Target. Any such communication or press release shall be subject to the other Party's consent not to be unreasonably withheld or delayed. For the avoidance of doubt, Licensee shall be permitted to disclose any information regarding the research, development, manufacturing, sale or marketing of the Licensed Product in press releases or other external communication, without Licensors prior written consent. Licensor shall not disclose any information regarding Licensed Product in press releases or other external communication, unless Licensee's written consent is obtained in advance. Neither Party shall have a right hereunder to publish or present any Confidential Information of the other Party.

15. Warranties

15.1 **By Licensor**. Licensor represents and warrants to Licensee, as of the Effective Date, that:

a) it has the full legal right and power to enter into the obligations and grant the rights set forth in this Agreement and that the performance of its obligations under and pursuant to this Agreement will not conflict with its articles of association or any agreements, contracts, or other arrangements to which it is a party;

b) with the exception of licenses granted by Licensor to Third Parties to the extent not barred by this Agreement, to the best knowledge of Licensor, it is the sole owner of the entire right, title and interest in and to the Licensed Patents free and clear of any liens, claims, encumbrances, or restrictions of any kind or nature;

c) to the best knowledge of Licensor, the use of the Affibody® Ligand(s) or ABD or the use of the Licensed Technology does not infringe any Third Party patent or other proprietary right. However, Licensor makes no representation or warranty that the Affibody® Ligand(s) or ABD or the use of the Licensed Technology, the Affibody® Ligand(s) or ABD alone or in combination with the Target will not infringe any Third Party patent or other proprietary right; and

d) Licensor has not received any claims from a Third Party that the Licensed Technology or the use thereof infringes or shall infringe any Third Party patent or other proprietary right.

15.2 **Disclaimer**. Except as expressly set forth in Section 15.1 above, Licensor disclaims all guarantees whatsoever with respect to the Affibody® Ligand(s), ABD, Licensed Technology and the Licensed Products, either express or implied. Without limiting the generality of the foregoing, there is no express or implied warranty: (i) of merchantability or fitness for a particular purpose, (ii) that any patent applications in the Licensed Patents will grant or that any Licensed Patents are valid, or (iii) that the use of the Affibody® Ligand(s), ABD or the Licensed Technology alone or in combination with the Target or any Licensed Product will not infringe any patent, copyright, trademark, or other rights. Licensee shall make no statements, representations, or warranties whatsoever to any Third Parties inconsistent with this Section 15.2.

15.3 **By Licensee.** Licensee represents and warrants to Licensor, as of the Effective Date, that it has the full legal right and power to enter into the obligations and that the performance of its obligations under and pursuant to this Agreement will not conflict with its articles of association or any agreements, contracts, or other arrangements to which it is a party.

16. Indemnity; Limitation of Liability.

16.1 **By Licensor.** Licensor shall defend, indemnify and hold harmless Licensee and its Affiliates and their respective employees, directors and agents ("**Representatives**"), from and against all losses, liabilities, claims, damages, settlements, judgments, awards, actions, suits and costs whatsoever, including reasonable attorneys' fees and disbursements and the costs of enforcing this indemnity (collectively, "**Losses**"), based upon, arising out of, or relating to, (i) any breach by Licensor of any of its representations and warranties under 15.1 of this Agreement, (ii) any material breach by Licensor of this Agreement, (iii) any claim, suits, actions, demands or judgments arising from or attributable to Licensor's (or its sublicensees') use of the Product Patents either outside the Field or the use of Product Patents and Product Technology under the circumstances set forth in Section 19.2 or 19.3; *except in each case*, to the extent such Losses result from the gross negligence or intent of Licensee or Licensee's Representatives, and further *provided* that Licensor has been notified promptly in writing of such claim, suit or proceeding and given authority, information (a written description of such claim and a copy of any legal papers served upon it which relate to such claim), and reasonable assistance (at Licensor's request and expense) to control the defense of any suit or proceeding.

16.2 **Specific Indemnity relating to [***].** Licensor shall defend, indemnify and hold harmless Licensee and its Affiliates and their respective Representatives from and against any Losses based upon, arising out of, or relating to the license agreement between Licensor and [***], which Licensor terminated as of [***], *provided* that Licensor has been notified promptly in writing of such claim, and given information, reasonable assistance, etc as described in Section 16.1 above. Licensor agrees in particular to pay (if necessary) any fees and royalties due to [***] for Licensee's exercise of the licenses granted by Licensor to Licensee in this Agreement.

16.3 **Sole Responsibility.** Licensor undertakes no responsibility for Licensee's, its Affiliates or Third Party Transferee's manufacture, marketing and sale of Licensed Products and/or other use of the Licensed Technology alone or in combination with the Target, including personal injury and other product liability, and Licensee shall have complete and exclusive responsibility for all activities concerning Licensee's, its Affiliates', and Third Party Transferees' use of the Licensed Technology.

16.4 **By Licensee.** Licensee shall defend, indemnify and hold harmless Licensor and its Representatives, from and against all Losses, based upon, arising out of, or relating to, (i) any breach by Licensee of any of its representations or warranties under Section 15.3, (ii) any material breach by Licensee of this Agreement or (iii) any claim, suits, actions, demands or judgments arising from or attributable to Licensee's, its Affiliates', and Third Party Transferees' use of the Licensed Technology alone or in combination with the Target (including but not limited to product liability claims); *except in each case*, to the extent such Losses result from the gross negligence or intent of Licensor or Licensor's Representatives, and further *provided* that Licensee has been notified without undue delay in writing of such claim, suit or proceeding and given authority, information (a written description of such claim and a copy of any legal papers served upon it which relate to such claim), and reasonable assistance (at Licensee's request and expense) to control the defense of any suit or proceeding.

16.5 **Indemnity Procedure.** The indemnifying Party shall not, without the prior written consent of the indemnified Party, agree to a settlement of any claim which could lead to liability or create any financial or other obligation on the part of the indemnified Party for which the indemnified Party is not entitled to indemnification hereunder. The indemnified Party shall cooperate with the indemnifying Party and shall always be entitled to participate in the defense or handling of such claim with its own counsel and at its own expense.

16.6 **Limitation of Liability.** With the exception of intentional acts or omissions, neither Party is liable to the other for any indirect or consequential damages of any kind such as lost profit, arising out of this Agreement and regardless of whether such Party shall be advised, shall have other reason to know, or in fact shall know of the possibility of the foregoing.

17. Insurance

Both Parties agree to maintain at their own cost and expense, while this Agreement is in effect, including any surviving obligations, a general liability insurance coverage that is reasonably adequate and customary in the insurance market in relevant locations and jurisdictions. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

18. Term and Termination

18.1 **Term.** Unless previously terminated in accordance with other provisions of this Agreement, this Agreement shall be in effect throughout the Term.

18.2 **Termination by Licensee.** Licensee shall have the right to terminate this Agreement, for any reason, (i) upon at least ninety (90) days prior written notice to Licensor and (ii) upon payment of any amounts due to Licensor through the effective date of such termination.

18.3 **Termination for Material Breach**. In the event that either Party ("**Breaching Party**") commits a material breach of its obligations under this Agreement, and fails to cure that breach within sixty (60) business days after receiving written notice thereof from the other Party ("**Terminating Party**"), the Terminating Party may terminate this Agreement immediately upon written notice to the Breaching Party.

18.4 **Termination for Insolvency, Bankruptcy**. In the event that a Party should be unable to pay its debts as they fall due, commence negotiations with any one or more of its creditors with a view to the general readjustment, moratorium or rescheduling of its indebtedness or make a general assignment for the benefit of. or enter into a composition or scheme of arrangement with, its creditors, or take any corporate action or other steps be taken or legal proceedings be started for its winding up, liquidation or dissolution, or file for company re-organization or bankruptcy, or be ordered into a compulsory winding-up or declared bankrupt, the other Party shall have the right to immediately terminate this Agreement upon written notice to the former Party.

18.5 **Termination for Patent Challenge**. If Licensee or any of its Affiliates or Third Party Transferees (a) commences or pursues (or assists Third Parties to do so, other than as required by law or legal process) any proceeding seeking to have any of the Licensed Patents, or any other of Licensor's patents or patent applications claiming or covering the Platform Technology, revoked or declared invalid, un-patentable, or unenforceable, or (b) commences or pursues (or assists Third Parties to do so, other than as required by law or legal process) any proceeding challenging the confidentiality or the substance of the Licensed Know-how, and/or the Platform Technology, Licensor may terminate this Agreement immediately upon written notice to Licensee.

19. Effect of Termination

19.1 **Survival**. The following provisions shall survive the termination or expiration of this Agreement, for any reason: Sections 2, 3.5, 7, 8.3, 9.5, 9.7, 9.8, 10.1 (for a period of three (3) years). 11, 13 (for a period of seven (7) years), 14, 16, 19, 20, 21, 22.1 and 22.3.

19.2 **Termination by Licensee for convenience or by Licensor.** Upon premature termination of this Agreement by Licensee in accordance with Section 18.2 above or by Licensor in accordance with Sections 18.3-18.5 above:

(i) all rights and licenses granted by Licensor to Licensee shall terminate;

(ii) if Licensor so requests. Licensee shall transfer all rights to the Product Technology, including for the avoidance of doubt, any Product Patent(s), free of charge to Licensee and to assist and issue necessary documents in order to secure such ownership on a worldwide basis. Until such transfer has been executed, the field of Licensor's licenses in Section 3.5 above shall automatically extend to include all uses (including the Field and the Target); and

(iii) any and all tangible manifestations and embodiments of Licensor's Confidential Information provided by or on behalf of Licensor pursuant to this Agreement shall be promptly returned by Licensee to Licensor or destroyed by Licensee.

19.3 **Regulatory Filings and Approvals.** Upon premature termination of this Agreement by Licensee for convenience in accordance with Section 18.2 above, Licensee shall grant Licensor an exclusive, royalty-free, perpetual right to use all regulatory filings, regulatory approvals and all data provided by Licensee to regulatory authorities in support of such regulatory filings or approvals, *in each case*, that are owned or controlled by Licensee, its Affiliates or Third Party Transferees of any of the foregoing and that relate solely to the Licensed Product. Licensee shall not be liable to Licensor for any reason whatsoever as consequence of Licensor's use of such regulatory filings, regulatory approvals or data. Licensee disclaims all guarantees whatsoever with respect to the regulatory filings, regulatory approvals or data, either express or implied. Without limiting the generality of the foregoing, there is no express or implied warranty: (i) of merchantability or fitness for a particular purpose, (ii) that the use of the regulatory filings, regulatory approvals or data will not infringe any patent, copyright, trademark, or other rights. Licensor shall make no statements, representations, or warranties whatsoever to any Third Parties inconsistent with this Section 19.3.

19.4 **Termination by Licensee for Material Breach.** Upon premature termination of this Agreement by Licensee in accordance with Section 18.3, Licensee shall retain its licenses and rights hereunder; *provided* that Licensee will remain bound by its obligations hereunder with respect to royalty and milestone payments, records, audit and indemnity, *except* that (i) Licensee shall be relieved to provide any information or reports to Licensor except as required for royalty reporting purposes and (ii) the royalty rates set forth in Section 9.4 under this Agreement shall, with respect to royalty payments due after the effective date of termination, be reduced to [***] (Licensed Product covered by a Valid Claim) and [***] (Licensed Product not covered by a Valid Claim), respectively, to compensate Licensee for the injury sustained due to the breach of contract,

19.5 **Termination by Licensee for Insolvency, Bankruptcy.** Upon premature termination of this Agreement by Licensee in accordance with Section 18.4 above, Licensee shall retain its licenses and rights hereunder; *provided* that Licensee will remain bound by its obligations hereunder with respect to royalty and milestone payments, records, audit and indemnity, but Licensee shall be relieved to provide any information or reports to Licensor except as required for royalty reporting purposes.

19.6 **Accrued obligations.** In no event shall termination of this Agreement release either Party from any accrued obligation, including Licensee's obligation to pay any amounts that became due on or before the effective date of termination.

20. Notices, etc.

20.1 Invoices submitted by Licensor to Licensee shall be sent to Swedish Orphan Biovitrum AB (publ), Leverantorsreskontra, FE 192, 838 80 Hackås, Sweden.

20.2 Any other written notice required to be given pursuant to this Agreement shall be deemed validly given if:

(i) signed by the Party giving that notice; and

(ii) sent by registered mail, or sent by facsimile transmission (provided that the sender's facsimile machine confirms transmission to the intended recipient) to the intended recipient's physical address or facsimile number, as set out below (or to such other physical address or facsimile number as the intended recipient shall notify to the other Party by written notice from time to time):

If to Licensor, to:

Affibody AB
Gunnar Asplunds Allé 24
SE-171 63 Solna
Sweden
Attn: CEO
Copy: SVP Operations
Facsimile No: [***]

If to Licensee, to:

Swedish Orphan Biovitrum AB (publ)
Tomtebodavagen 23 A, SE-112 76 Stockholm, Sweden
Attn: Vice President, Corporate Development
Copy: General Counsel
Facsimile No: [****]

20.3 For the purposes of this Agreement, any notice transmitted by facsimile or delivered after 5.00pm on a business day, or at any time on a non-business day, shall be deemed received at 9.00am on the next business day.

21. Governing law; Arbitration

21.1 **Governing Law**. This Agreement shall be governed by Swedish law, without regard to conflict of laws principles.

21.2 **Arbitration**. Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof, shall be finally settled by arbitration administered by the Arbitration Institute of the Stockholm Chamber of Commerce under the Rules of the Arbitration Institute. The arbitration proceedings shall be held in Swedish. The place of arbitration shall be Stockholm, Sweden.

22. Miscellaneous

22.1 **Perpetual Rights**. For the avoidance of doubt, any perpetual licenses granted under this Agreement in respect of intellectual property rights, which may subsist indefinitely, shall extend for a period of thirty (30) years.

22.2 **Entire Agreement**. This Agreement represents the entire understanding between the Parties, and supersedes all other agreements, express or implied, between the Parties concerning the subject matter hereof, and shall not be subject to any change or modification except by the execution of a written instrument duly signed by the Parties hereto.

22.3 **Assignment**. Neither this Agreement nor any of the rights and obligations arising hereunder may be assigned or transferred by either Party without the prior written consent of the other Party such consent not to be unreasonably withheld. Notwithstanding the foregoing, either Party may assign this Agreement to any Affiliate of such Party or to any purchaser of all or substantially all of the Party's assets or the respective business.

22.4 **Relationship of the Parties**. Each Party is an independent contractor and neither Party has, nor shall have, any power, right or authorization to bind the other or to assume or create any obligations or responsibilities, express or implied, on behalf of the other or in the other's name. The Swedish Act (1980:1102) on Trading Partnerships and Simple Partnerships shall not apply to this Agreement.

This Agreement has been executed in two (2) identical original copies of which the Parties have taken one each.

Affibody AB

By: /s/ David Bejker
Name: David Bejker
Title: CEO

Swedish Orphan Biovitrum AB (publ)

By: /s/ Geoffrey McDonough
Name: Geoffrey McDonough
Title: CEO

By: /s/ Fredrik Berg
Name: Fredrik Berg
Title: General Counsel

Appendices:

A. List of Affibody® Ligand(s)

B. Patents and patent applications claiming the Affibody® Molecule Technology

C. Patents and patent applications claiming the Albumin Binding Technology

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

AMENDMENT NO 1 TO C5 PLA

THIS AMENDMENT NO 1 to the Product License Agreement dated March 9, 2012, as subsequently supplemented by a Letter Agreement dated November 4, 2015 (the "**C5 PLA**"), is entered into with effect as of January 1, 2018 (the "**Effective Date**"), and made between:

(1) **Affibody AB**, corp. reg. no 556665-6913, Gunnar Asplunds Allé 24, SE-171 63 Solna ("**Affibody**")**;** and

(2) **Swedish Orphan Biovitrum AB** (**publ**), corp. reg. no 556038-9321, SE-112 76 Stockholm ("**Licensee**").

Affibody and Licensee are collectively referred to as the "Parties".

1. BACKGROUND INFORMATION

1.1 Affibody and Licensee will, together with third parties, participate within a [***] funded research project named *"[***]"* (the "***[***]***"). The parties to the [***] have executed a [***] dated [***] "("**[***]**"), and may execute additional agreements within the scope of the [***]. The Main Agreement and any such agreements are jointly referred to as "***[***]***".

1.2 Sobi wishes to use a specific Affibody® Ligand in the [***].

1.3 In view of this, the Parties hereby agree as follows.

2. AMENDMENTS

2.1 Notwithstanding the provisions of the C5 PLA, including section 3.6, Licensee may use the Affibody® Ligand included in [***] (as specified in Appendix A) in research project carried out within the scope of the [***], and in connection therewith transfer and make available such Affibody® Ligand to the other parties in the [***].

2.2 Licensee agrees that the C5 PLA, including Licensee's exclusive licenses and Target exclusivity pursuant to section 5 of the C5 PLA, does not preclude Affibody from participating in the [***]. In addition, each of Affibody's and Licensee's rights under the C5 PLA are subject to any conflicting obligations of Licensee and Affibody, as the case may be, to provide access rights to intellectual property under the [***] (including *"[***]"* and *"[***]"* as defined therein) to the other parties in the [***].

2.3 Notwithstanding clause 2.2 above, as between the Parties, any *"[***]"*, shares in *"[***]"* and *"[***]"* (each term as defined in the Main Agreement) generated and/or owned by any of Affibody and Licensee under the [***], and relating to the Product Technology (including the Affibody® Ligand(s)) or the Platform Technology jointly referred to as "[***]"), shall be treated as if such [***] and corresponding intellectual property rights had been generated under the scope of the C5 PLA. This means e.g. that any Improvements

to the Affibody® Ligand(s) as such shall be considered as Product Technology, and that any Improvements to the Affibody® Molecule Technology shall be considered as Platform Technology. Likewise, any patents and patent applications covering [***] shall be treated as Licensed Patents or Product Patents, as and when applicable, and the term "Valid Claim" under the C5 PLA, and Licensee's royalty obligations under the C5 PLA shall include also such patents and patent applications. For this purpose, each of Affibody and Licensee agrees to sign, and cause its employees and consultants to sign, such documents and take such other measures deemed necessary and required by the other Party to secure a transfer of such [***] in accordance with this clause 2.3.

2.4 If it is not possible to allocate [***] between Affibody and Licensee as stated in clause 2.3, e.g. due to legal or contractual restrictions under the [***], then the affected Party shall fulfil any obligations relating to such [***] on behalf of the other Party, which shall acquire such income and rights pursuant thereto that would otherwise have been due if such transfer actually had occurred, and the Parties shall endeavor to negotiate a substitute arrangement that best reflects the economic intentions of the Parties without being unenforceable, and shall execute all agreements and documents required in this respect. For the avoidance of doubt, this is not intended to amend section 22.4 of the C5 PLA *(Relationship of the Parties).*

2.5 Each Party agrees to consult with the other Party before granting rights to the other parties in the [***] to [***] or other intellectual property rights that are covered by the C5 PLA.

3. OTHER

3.1 Except as modified hereby, the C5 PLA shall remain in full force and effect between the Parties. Capitalized terms used in this Amendment No 1 shall have the same meaning as set out in the C5 PLA unless explicitly stated otherwise.

3.2 If there is a conflict between the terms of the C5 PLA and this Amendment No 1, this Amendment No 1 shall control as to the [***].

3.3 For clarity, the provisions on confidentiality (section 13),indemnity, etc. (section 16), and choice of law and arbitration (section 21) in the C5 PLA shall apply also to this Amendment No 1.

AFFIBODY AB

/s/ David Bejker
David Bejker, CEO

SWEDISH ORPHAN BIOVITRUM AB (PUBL)

/s/ Carin Dahlquist
Carin Dahlquist, Associate GC

/s/ Kirsti Gjellan
Kirsti Gjellan, SVP, Head of Manufacturing Operations

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

AMENDMENT NO 2 TO C5 PLA

THIS AMENDMENT NO 2 to the Product License Agreement dated March 9, 2012, as subsequently supplemented by a Letter Agreement dated November 4, 2015 and amended by Amendment No. 1 dated January 1, 2018 (the "**C5 PLA**"), is entered into with effect as of 22 December 2020, and made between:

(1) **Affibody AB**, corp. reg. no 556665-6913, Scheeles väg 2, SE-171 65 Solna, Sweden ("Licensor"); and

(2) **IPC Research, LLC**, a Delaware company and a wholly-owned subsidiary of Rallybio Holdings, LLC, 234 Church Street, Suite 1020, New Haven, CT 06510, USA ("**Licensee**").

Affibody and Licensee is each a "**Party**" and are collectively referred to as the "**Parties**".

1. BACKGROUND INFORMATION

1.1 The Parties are parties to the C5 PLA, following an assignment from the original licensee Swedish Orphan Biovitrum AB (publ) ("**Sobi**") to Licensee, under which Sobi assigned and transferred all of Sobi's rights and obligations under the C5 PLA to Licensee, and Licensee substituted Sobi as a party to the C5 PLA.

1.2 Licensor and Licensee, respectively, have filed new patent applications claiming *inter alia* Affibody® Ligand(s) as well as other Target binding Affibody® Molecules in several countries.

1.3 Patent applications filed by Licensor include international patent application [***] and [***] and that is listed in Appendix 1 hereto (collectively the "**Affibody Applications**"), including, but not limited to Affibody's [***] (the "**Affibody [***] Application**"). The Affibody Applications relate to Improvements to the Affibody® Molecule Technology that were made, conceived or reduced to practice by employees of Sobi prior to the date Licensee substituted for Sobi as described in Section 1.1 of this Amendment No. 2, and subsequently assigned to Licensor in accordance with Section 11.1 of the C5 PLA, and constitute Licensed Patents.

1.4 Patent applications filed by Licensee include international patent application [***] and [***] (collectively the "Licensee Applications") including, but not limited to, Licensee's [***] (the "**Licensee [***] Application**"). The Licensee Applications relate to Affibody® Molecules that bind to the Target, including Affibody® Ligands (which include those molecules for which amino acid sequences of the C5 (i.e. Target) binding motif are provided in the Licensee Applications), and therefore constitute Product Patents, but also relate to other Affibody® Molecules binding to the Target (which thus are not Affibody® Ligands)).

1.5 As contemplated by Sections 2.4 and 3.4 of the C5 PLA, Licensee has notified Licensor that it wishes to have a license to Improvements to the Affibody® Molecule Technology, and accordingly the Parties have agreed to add the Affibody Applications to the list of Licensed Patents in Appendix B of the C5 PLA as set forth in this Amendment No. 2.

1.6 In the light of the fact that the [***] recently rejected the Affibody [***] Application and the Licensee [***] Application on the basis that the applications had overlapping claims, the Parties have also executed this Amendment No. 2 to regulate their agreement in relation to the Affibody [***] Application and the Licensee [***] Application, and to set forth their intention to work together in good faith to address any similar issues that have arisen or may arise with respect to any other Affibody Applications or Licensee Applications in any country.

1.7 The Parties have further agreed to re-establish the Information Sharing Committee ("ISC") as set forth in this Amendment No. 2.

2. AMENDMENTS

2.1 **Limitation of Affibody [***] Application**. Subject to the terms and conditions of this Amendment No. 2, and the additional licenses granted to Licensor herein, Licensor agrees to amend, and has amended, the claims of the Affibody [***] Application to remove Affibody® Molecules binding to the Target from the claim scope. To the extent that, notwithstanding these amendments, the claim scope of the Affibody [***] Applications still includes any Affibody® Molecules binding to the Target, Affibody hereby grants to Licensee a license under such Affibody [***] Application that is exclusive with respect to the use of the Affibody Ligands within the Field, to mirror what is set out in Section 3.1b) of the C5 PLA.

2.2 **Additional Exclusive License Relating to Licensee** [***] **Application**. The license granted by Licensee to Licensor under the Product Patent(s) pursuant to Section 3.5 of the C5 PLA shall, in relation to the Licensee [***] Application only, be amended by inserting a new Section 3.5A immediately after Section 3.5 as follows:

"3.5A Licensee hereby grants to Licensor:

a) An exclusive, royalty-free, perpetual, irrevocable license (including the right to grant sub-licenses) in [***] under the Licensee [***] Application, for all uses and applications (including but not limited to the use of Affibody® Ligands), outside the Field; and

b) A non-exclusive royalty-free, perpetual, irrevocable license (including the right to grant sub-licenses) in [***] under any Know-how relating to the Licensee [***] Application, which is directly related to the use of any Affibody Ligand(s) as such or the use of Affibody Molecule® Technology, to the extent necessary for Licensor to practice the Licensee [***] Application outside the Field in accordance with Section 3.5Aa) above (as amended by this Amendment No. 2). For clarity, this non-exclusive license is only intended to allow Licensor and its sub-licenses freedom to operate under the Licensee [***] Application as set out in Section 3.5Aa) (as amended herein) and not for any other purpose. Licensee will further not be required to perform any technological transfer or "show-how" or similar activities as a consequence of this license."

2.3 **Updated list of Licensed Patents**. Appendix B of the C5 PLA contains a list of patents and patent applications claiming the Affibody® Molecule Technology, which constitute Licensed Patents. Such Appendix B is hereby updated to add the Affibody Applications, as set out in Appendix 1 herein.

2.4 **Co-operation on Affibody Applications and Licensee Applications**. Each Party agrees to notify the other Party of any objection to or rejection of an Affibody Application or a Licensee Application by a patent authority that relates to the co- existence of an Affibody Application and a Licensee Application (such as, for example, any double-patenting rejections or any rejection otherwise relating to an overlap in the scope of an Affibody Application and a Licensee Application), and to cooperate in good faith with the other Party on the response to any such objection or rejection with the intention that, to the greatest extent reasonably possible, the response to any such objection or rejection is agreeable to both Parties, *provided*, that if the Parties are unable to agree following good faith discussions for a reasonable period of time, each Party shall be free to submit its response as it deems required. In the event that either Party notifies the other Party that it wishes to further amend the C5 PLA to address any such objection to or rejection of an Affibody Application or a Licensee Application, or the response thereto, in any country, and/or to include any additional licenses necessitated thereby, the Parties agree to discuss and negotiate in good faith any such further amendments to the C5 PLA. All such good faith cooperation and discussions will aim to achieve an outcome that as closely as possible reflects having the Affibody Application(s) and Licensee Application(s) being granted as coexisting patents and to reflect the license grants under the C5 PLA, and will otherwise be based on the principles set out in this Amendment No 2.

2.5 **Reestablishment of Information Sharing Committee**. The Parties have agreed to re-establish the ISC. What is stated in Sections 6.2 and 6.2 a) of the C5 PLA shall apply except that Section 6.2 b) of the C5 PLA shall be amended as follows:

"The ISC shall meet (either in person or by telephone conference) at least once every six (6) months until the First Commercial Sale."

3. OTHER

3.1 Except as modified hereby, the C5 PLA shall remain in full force and effect between the Parties. Capitalized terms used in this Amendment No 2 shall have the same meaning as set out in the C5 PLA unless explicitly stated otherwise.

3.2 If there is a conflict between the terms of the C5 PLA and this Amendment No 2, this Amendment No 2 shall prevail.

3.3 For clarity, the provisions on confidentiality (section 13), indemnity, etc. (section 16), and choice of law and arbitration (section 21) in the C5 PLA shall apply also to this Amendment No 2.

Signatures follow

AFFIBODY AB

/s/ David Bejker
David Bejker, CEO

IPC RESEARCH, LLC

/s/ Stephen Uden
Stephen Uden,

Exhibit 10.7
As amended, as of January 20, 2021

RALLYBIO HOLDINGS, LLC

2018 SHARE PLAN

I. GENERAL

1.1. **Purpose.**

The purpose of this equity incentive plan (the "Plan") is to secure for Rallybio Holdings, LLC, a Delaware limited liability company (the "Company"), and its members the benefits arising from equity ownership by employees, officers and managers of, and consultants or advisors to, the Company and any affiliate of the Company who are in a Business Relationship with the Company and are expected to contribute to the Company's future growth and success. The Plan permits grants of options to purchase Common Shares and awards of Common Shares.

Capitalized but otherwise undefined terms herein shall have the meanings ascribed to them in Section 6.16 hereof.

1.2. **Plan Administration: General.**

(a) Administration. The Plan shall be administered by the Board of Managers of the Company (the "Board of Managers"), whose construction and interpretation of the terms and provisions of the Plan shall be final and conclusive. The Board of Managers may in its discretion grant Common Shares and options to purchase Common Shares and issue Common Shares upon exercise of such options as provided in the Plan. The Board of Managers shall have authority, subject to the express provisions of the Plan, to construe the respective option and share agreements and the Plan, to prescribe, amend and rescind rules and regulations relating to the Plan, to determine the terms and provisions of the respective option and share agreements and to make all other determinations in the judgment of the Board of Managers necessary or desirable for the administration of the Plan. The Board of Managers may correct any defect or supply any omission or reconcile any inconsistency in the Plan or in any option or share agreement in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. No manager or person acting pursuant to authority delegated by the Board of Managers shall be liable for any action or determination under the Plan made in good faith. The Board of Managers may, to the full extent permitted by or consistent with applicable laws or regulations (including, without limitation, applicable state law) delegate any or all of its powers under the Plan to a committee (the "Committee") appointed by the Board of Managers, and if the Committee is so appointed, all references to the Board of Managers in the Plan shall mean and relate to such Committee with respect to the powers so delegated. In the event that the Company has a Manager rather than a Board of Managers, all references to the Board of Managers in the Plan shall mean and relate to such Manager.

(b) Option or Common Share Awards to Managers. Any Manager (as defined in the Operating Agreement) to whom an option or award of Common Shares is granted shall be ineligible to vote upon his or her option or Common Share grant, but such option or Common Share grant may be awarded to any such Manager by a vote of the remainder of the Managers, except as limited below.

1.3. **Eligibility.**

Options and Common Shares may be granted to persons who are, at the time of grant in a Business Relationship with the Company. A person who has been granted an option or Common Shares may, if otherwise eligible, be granted additional options or Common Shares if the Board of Managers shall so determine. For purposes of the Plan, the Business Relationship is considered as continuing during a period in which a recipient of a grant is on military or sick leave or other bona fide leave of absence, as long as the leave does not exceed 90 days, and a leave that lasts longer than 90 days shall not be considered an interruption of the Business Relationship if such recipient's right to return to the Business Relationship is guaranteed by contract or statute.

1.4. **Common Shares Subject to Plan.**

The Common Shares or the Common Shares subject to options granted under the Plan shall be authorized but unissued or reacquired Common Shares. Subject to adjustment as provided in Section 6.2, the maximum number of Common Shares which may be issued and sold under the Plan is Twenty-Two Million Nine Hundred Seventy-Two Thousand Three Hundred Sixty (22,972,360). If any Common Shares granted under the Plan are reacquired by the Company or forfeited or if an option granted under the Plan shall expire, terminate or is canceled for any reason without having been exercised in full, such reacquired or forfeited Common Shares or unpurchased Common Shares subject to such option shall again be available for subsequent option or Common Share grants under the Plan.

1.5. **Option and Share agreements.**

(a) Agreements. As a condition to the grant of Common Shares or an option under the Plan, each recipient of Common Shares or an option shall execute a share or an option agreement in such form not inconsistent with the Plan as may be approved by the Board of Managers. Such share or option agreements may differ among recipients.

(b) Additional Provisions. The Board of Managers may, in its discretion, include additional provisions in option or share agreements covering options or Common Shares granted under the Plan, including without limitation, restrictions on transfer, repurchase rights, rights of first refusal, commitments to pay cash bonuses, to make, arrange for or guaranty loans or to transfer other property to optionees upon exercise of options or such other provisions as shall be determined by the Board of Managers; provided, that such additional provisions shall not be inconsistent with any other term or condition of the Plan or the Operating Agreement.

II. OPTIONS

2.1. **Exercise Price; Payment.**

(a) Exercise Price. The exercise price per Common Share deliverable upon the exercise of an option (each, an "Option Common Share") shall be determined by the Board of Managers at the time of grant of such option; provided, however, that the exercise price shall not be less than 100% of the Fair Market Value of such Common Share at the time of grant of such option.

(b) Payment of Exercise Price. Options granted under the Plan may provide for the payment of the exercise price by delivery of cash or a check to the order of the Company in an amount equal to the exercise price of such options, or, to the extent provided in the applicable option agreement, (i) by delivery to the Company of Common Shares having a Fair Market Value on the date of exercise equal in amount to the exercise price of the options being exercised, (ii) by any other means (including, without limitation, by delivery of a promissory note of the optionee payable on such terms as are specified by the Board of Managers) which the Board of Managers determines are consistent with the purpose of the Plan and with applicable laws and regulations or (iii) by any combination of such methods of payment.

(c) Cashless Exercise. Notwithstanding the provisions of Section 2.2(b) to the contrary, if approved by the Board of Managers and if the Fair Market Value of one Common Share for which an option is being exercised is greater than the exercise price on the date of exercise, in lieu of paying the exercise price in cash, an optionee may elect upon exercise to receive that number of Common Shares equal to the value (as determined below) of the Common Shares for which the option is being exercised minus the exercise price by delivering notice of such election to the Company, in which event the Company shall issue to the optionee a number of such Common Shares computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where X = the number of Common Shares to be issued to the optionee
Y = the number of Common Shares to be exercised
A = the Fair Market Value of one Common Share (at the date of exercise)
B = exercise price (as adjusted to the date of such calculation).

2.2. **Exercise of Options.**

(a) Timing; Acceleration: Extension. Each option granted under the Plan shall be exercisable either in full or in installments at such time or times and during such period as shall be set forth in the option agreement evidencing such option, subject to the provisions of the Plan. Subject to the requirements in the immediately preceding sentence, if an option is not at the time of grant immediately exercisable, the Board of Managers may (i) in the option agreement, provide for the acceleration of the exercise date or dates of the subject option upon the occurrence of specified events, (ii) at any time prior to the complete termination of an option, accelerate the date or dates on which all or any particular option or options granted under the Plan may be exercised and/or (iii) extend the date or dates on which all or any particular option or options granted under the Plan may be exercised.

(b) Fractional Common Shares. The Company shall not be required to deliver any fractional Common Shares, but shall pay, in lieu thereof, the Fair Market Value (determined as of the date of exercise) of such fractional Common Share to the optionee or the optionee's beneficiary or estate, as the case may be.

(c) Expiration of Options. Subject to earlier termination as provided in the Plan, each option and all rights thereunder shall expire on such date as determined by the Board of Managers and set forth in the applicable option agreement; provided that such date shall not be later than ten years after the date on which the option is granted.

(d) Operating Agreement. If the optionee is not already a party thereto, the optionee shall deliver an executed counterpart of the Operating Agreement or a joinder agreement making the optionee a party to the Operating Agreement (which is incorporated by reference herein and which in all cases shall control in the event of any conflict with the terms, definitions and provisions of the Plan). A copy of the Operating Agreement as in effect on the date hereof has been supplied to the optionee, and the optionee hereby acknowledges receipt thereof. The optionee understands and acknowledges that optionee will be required to sign the Operating Agreement or a joinder agreement making the optionee a party to the Operating Agreement as a condition to the exercise of an option. The rights of the Company and obligations of the optionee contained herein or in any option agreement issuing options under the Plan shall be in addition to, and not exclusive of, any rights of the Company or obligations of the optionee contained in the Operating Agreement.

2.3. **Nontransferability of Options.**

Unless otherwise permitted by the Board of Managers, no option granted under the Plan may be Transferred by the optionee except by will or by the laws of descent and distribution or pursuant to a qualified domestic relations order as defined in the Code or Title I of ERISA, or the rules thereunder. An option may be exercised during the lifetime of the optionee only by the optionee or in the event the optionee is incapacitated, by such person with power of attorney for the optionee. If any optionee should attempt to Transfer the optionee's options, other than in accordance with the applicable terms of the Plan or the applicable option agreement, the optionee's interest in such options shall terminate.

2.4. **Effect of Termination of Business Relationship, Death or Disability.**

(a) Termination of Business Relationship; Death or Disability. Subject to the provisions of the Plan, an optionee may exercise an option (but only to the extent such option was exercisable at the time of termination of the optionee's Business Relationship with the Company) at any time within three months (unless otherwise specified in the applicable option agreement) following the termination of the optionee's Business Relationship with the Company or within one year (or within such lesser period as may be specified in the applicable option agreement) if such termination was due to the death or disability of the optionee, but in no event later than the expiration date of the option.

(b) Termination for Cause or Upon Breach. If the termination of the optionee's Business Relationship is for cause or is otherwise attributable to a breach by the optionee of an agreement between the Company and the optionee, including without limitation an employment, confidentiality, noncompetition, non-disclosure or other material agreement (a "Company Agreement"), all outstanding options shall expire immediately upon such termination. The Board of Managers shall have the power to determine what constitutes a termination for cause or a breach of a Company Agreement, whether an optionee has been terminated for cause or has breached such an agreement and the date upon which such termination for cause or breach occurs. Any such determinations shall be final and conclusive and binding upon the optionee. In addition to the foregoing, all outstanding options shall expire immediately, if, at any time following termination of the Business Relationship, the optionee breaches any Company Agreement that survives termination of the Business Relationship.

2.5. **Suspension of Option.**

The Company may suspend for a reasonable period or periods the time during which any option granted pursuant to the Plan may be exercised if, in the opinion of the Company, such suspension is required to enable the Company to remain in compliance with regulatory requirements relating to the issuance of Common Shares.

2.6. **Cancellation and New Grant of Options, Etc.**

The Board of Managers shall have the authority to, at any time and from time to time, with the consent of a majority of the affected optionees: (a) cancel any or all outstanding options under the Plan and the grant in substitution therefor new options under the Plan covering the same or different numbers of Common Shares and having the same or different exercise price; or (b) amend the terms of any and all outstanding options under the Plan to provide for a different exercise price.

2.7. **Rights as a Member.**

An optionee shall have no rights as a member with respect to any Option Common Shares (including, without limitation, any rights to receive distributions with respect to such Common Shares) until the date of issue of Common Shares to the optionee for such Option Common Shares. No adjustment shall be made for distributions or other rights for which the record date is prior to the date such option is so exercised.

III. COMMON SHARE AWARDS

3.1. **General.**

The Board of Managers may from time to time in its discretion award Common Shares to individuals or entities in a Business Relationship with the Company (a "Recipient") and may determine the number of Common Shares awarded and the terms and conditions thereof including the amount of payment, if any, to be made by a Recipient for such Common Shares. Any Common Shares awarded under the Plan shall be subject to the terms and conditions of the Operating Agreement. If the Recipient is not already a party thereto, the Recipient shall deliver an executed counterpart of the Operating Agreement or a joinder agreement making the Recipient a party to the Operating Agreement (which is incorporated by reference herein and which in all cases shall control in the event of any conflict with the terms, definitions and provisions of the Plan). A copy of the Operating Agreement as in effect on the date hereof has been supplied to the Recipient, and the Recipient hereby acknowledges receipt thereof. The Recipient understands and acknowledges that Recipient will be required to sign the Operating Agreement or a joinder agreement making the Recipient a party to the Operating Agreement as a condition to the receipt of Common Shares. The rights of the Company and obligations of the Recipient contained herein or in any restricted share agreement granting Common Shares pursuant to the Plan shall be in addition to, and not exclusive of, any rights of the Company or obligations of the Recipient contained in the Operating Agreement.

3.2. **Restricted Period: Lapse of Restrictions.**

At the time an award of Common Shares is made that is subject to vesting ("Unvested Common Shares"), the Board of Managers shall establish a period of time during which such award shall vest (the "Restricted Period"). Each award of Unvested Common Shares may have a different Restricted Period. In lieu of establishing a Restricted Period, the Board of Managers may establish restrictions based only on the achievement of specified performance measures. At the time an award is made, the Board of Managers may, in its discretion, prescribe conditions for the incremental lapse of restrictions during the Restricted Period and for the lapse of restrictions upon the occurrence of other conditions in addition to or other than the expiration of the Restricted Period with respect to all or any portion of the Unvested Common Shares. Such conditions may include, without limitation, the death or disability of the Recipient, retirement of the Recipient or termination by the Company of the Recipient's Business Relationship other than for cause or the occurrence of a Change of Control (as defined in Section 6.3(a)). The Board of Managers may also, in its discretion, shorten or terminate the Restricted Period or waive any conditions for the lapse of restrictions with respect to all or any portion of the Unvested Common Shares at any time after the date the award is made.

3.3. **Rights of Holder; Limitations Thereon.**

The Recipient shall generally have the rights and privileges of a member as to Common Shares awarded to the Recipient under the Plan, including the right to vote such Common Shares, except that all of the Unvested Common Shares as to which restrictions have not at the time lapsed shall be forfeited and all rights of the Recipient (other than the right to receive the price paid, if any, by the Recipient for the Unvested Common Shares) to such Unvested Common Shares shall terminate without further obligation on the part of the Company unless the Recipient has maintained a Business Relationship with the Company until the expiration or termination of the Restricted Period and the satisfaction of any other conditions prescribed by the Board of Managers applicable to such Unvested Common Shares. A Recipient may not Transfer any or all of the Recipient's Common Shares except to the extent permitted by the Plan and the Operating Agreement. Upon the forfeiture of any Unvested Common Shares, such forfeited Common Shares shall be transferred to the Company without further action by the Recipient. At the discretion of the Board of Managers, cash and other distributions with respect to the Unvested Common Shares may be either currently paid or withheld by the Company for the Recipient's account and interest shall be paid on the amount of such distributions withheld at four (4) percent annually. The Recipient shall have the same rights and privileges, and be subject to the same restrictions, with respect to any Common Shares received pursuant to Section 6.2 hereof. The Company shall not be required to deliver any fractional Common Share but shall pay, in lieu thereof, the Fair Market Value (determined as of the date the conditions for the receipt of Common Share are satisfied) of such fractional Common Share to the Recipient or the Recipient's beneficiary or estate, as the case may be.

IV. FAIR MARKET VALUE

"Fair-'Market Value" of a Common Share shall be determined in good faith by the Board of Managers by the application of a reasonable valuation method, including, but not limited to, any applicable safe harbor valuation method described in Treasury Regulation §1.409A- 1 (b) (5) (iv) (B).

V. COMPANY'S RIGHT OF FIRST REFUSAL AND FORFEITURE OF COMMON SHARES

5.1. **Company's Right of First Refusal.**

(a) Required Notice. If a holder of Common Shares granted, purchased or awarded under the Plan proposes to Transfer any such Common Shares, the holder shall promptly give written notice (the "Notice") to the Company at least 45 days prior to the contemplated closing of such Transfer. The Notice shall describe in reasonable detail the proposed Transfer including, without limitation, the number of Common Shares to be Transferred, the nature of such Transfer, the consideration to be paid and the name and address of each prospective purchaser or transferee. In the event that the Transfer is being made pursuant to the provisions of Section 5.1 (d), the Notice shall state under which clause of such Section the holder proposes to make such Transfer.

(b) Exercise Period. For a period of ten days following receipt of any Notice described in Section 5.1 (a), the Company shall have the right to purchase all or a portion of the Common Shares subject to such Notice on the same terms and conditions as set forth therein (the "Right of First Refusal"). The Right of First Refusal shall be exercised by written notice signed by an officer of the Company and delivered to the holder within such ten day period. The Company shall effect the purchase of the Common Shares, including payment of the purchase price, by the later of (i) the date specified in the Notice as the intended date of the Transfer or (ii) 30 days after receipt of the Notice, and at such time the holder shall endorse and deliver to the Company the share certificates representing the Common Shares being purchased by the Company, each certificate to be properly endorsed for transfer and accompanied by duly executed stock powers. The Common Shares so purchased shall thereupon be cancelled and cease to be issued and outstanding. The Right of First Refusal shall terminate with respect to any Transfer for which it has not been timely exercised pursuant to this Section 5.1 (b).

(c) Attachment of Right; Cessation of Rights. The Right of First Refusal shall attach to the Common Shares granted, purchased or awarded under the Plan and all Transfers of such Common Shares shall be subject to the Right of First Refusal. The holder of Common Shares subject to the Right of First Refusal shall cease to have any rights with respect to such Common Shares immediately upon receipt of the purchase price pursuant to the exercise by the Company of its Right of First Refusal.

(d) Exceptions. Notwithstanding the foregoing, the provisions of this Section 5.1 shall not apply to any Transfer (i) that is made for bona fide estate or tax planning purposes, either during the lifetime of a holder or on death by will or intestacy to his or her spouse, child (natural or adopted) or any other direct lineal descendant of such holder (or his or her spouse) (all of the foregoing collectively referred to as "family members"), or any other person approved by the Board of Managers of the Company, or any custodian or trustee of any trust, corporation, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such holder or any such family members; provided that the holder (or such holder's representative in the case of death) shall deliver prior written notice to the Company of

such Transfer and such Common Shares shall at all times remain subject to the terms and restrictions set forth in the Plan and such transferee shall, as a condition to such issuance, agree to be bound by all the terms and conditions of the Plan (but only with respect to such Common Shares) and, provided further, that such Transfer is made pursuant to a transaction in which there is no consideration actually paid for such Transfer, (ii) to any person occurring as a matter of law upon the death or declaration of incompetence of a holder so long as the Transferee agrees in writing to be bound by the Plan, (iii) to the Company or (iv) by merger or share exchange or an exchange of existing shares for other shares of the same or a different class or series in the Company.

5.2. **Forfeiture of Common Shares.**

(a) Forfeiture. All unrestricted Common Shares granted, purchased or awarded under the Plan shall be subject to forfeiture at the option of the Company in the event the holder's Business Relationship with the Company is terminated for cause or due to a breach by the holder of any Company Agreement. The Company shall have 60 days after the date of such termination to exercise such option with respect to any or all of such Common Shares. All Unvested Common Shares granted, purchased or awarded under the Plan shall be forfeited in the event the Recipient's Business Relationship with the Company is terminated by the Company or the Recipient fails to satisfy any other conditions prescribed by the Board of Managers. The holder of Common Shares subject to forfeiture shall cease to have any rights with respect to such Common Shares immediately upon their forfeiture in accordance with this paragraph.

(b) Exercise; Transfer of Share Certificates. If the Business Relationship of an optionee or Recipient with the Company is terminated for cause or breach by the optionee or Recipient of a Company Agreement, the Company or its assignee shall have 60 days after the date of such termination to effect the forfeiture with respect to any or all of such optionee's or Recipient's Common Shares by delivering notice to such optionee or Recipient. If the Company or its assignee effects a forfeiture, the optionee or Recipient shall endorse and deliver to the Company or its assignee, as the case may be, the share certificates, if any, representing the Common Shares being forfeited, each certificate to be properly endorsed for transfer and accompanied by duly executed stock powers, and the Company or its assignee, as the case may be, shall upon such delivery refund the optionee or Recipient the purchase price, if any, such optionee or Recipient originally paid for such Common Shares. Thereupon, the Company shall cancel on its books the certificate(s) representing such Common Shares. The Company's right to so effect a forfeiture shall terminate with respect to any Common Shares for which it has not been timely exercised pursuant to this Section 5.2(b).

(c) Cessation of Rights. The holder of Common Shares subject to forfeiture shall cease to have any rights with respect to such Common Shares immediately upon their forfeiture in accordance with this Section 5.2.

5.3. **Company's Right to Repurchase.**

(a) Repurchase Right. All unrestricted Common Shares granted, purchased or awarded under the Plan shall be subject to a right (but not an obligation) of repurchase by the Company or its assignee in the event the Recipient's or optionee's Business Relationship with the Company is terminated for any reason other than cause or breach by the holder of a Company Agreement (the "Repurchase Right").

(b) Exercise Period. If the Business Relationship of an optionee or Recipient with the Company is terminated for any reason other than cause or breach by the optionee or Recipient of a Company Agreement, the Company or its assignee shall have 60 days after the date of such termination to exercise its Repurchase Right with respect to any or all of such optionee's or Recipient's Common Shares at Fair Market Value. If the Company or its assignee exercises its Repurchase Right, the optionee or Recipient shall endorse and deliver to the Company or its assignee, as the case may be, the share certificates, if any, representing the Common Shares being repurchased, each certificate to be properly endorsed for transfer and accompanied by duly executed stock powers, and the Company or its assignee, as the case may be, shall upon such delivery pay the optionee or Recipient the Fair Market Value purchase price. Thereupon, the Company shall cancel on its books the certificate (s) representing such Common Shares. The Repurchase Right shall terminate with respect to any Common Shares for which it has not been timely exercised pursuant to this Section 5.3(b).

(c) Attachment of Right; Termination. The Repurchase Right shall attach to the Common Shares granted, purchased or awarded under the Plan and all Transfers of such Common Shares shall be subject to the Repurchase Right. The holder of Common Shares subject to the Repurchase Right shall cease to have any rights with respect to such Common Shares immediately upon receipt of the Fair Market Value purchase price pursuant to the exercise by the Company or its assignee of its Repurchase Right. The Repurchase Right referred to in this Section 5.3 shall terminate upon the consummation of a firm commitment underwritten public offering of the Common Shares of the Company registered under the Securities Act of 1933, as amended (the "Securities Act").

VI. MISCELLANEOUS

6.1. **General Restrictions.**

(a) Investment Representations. The Company may require a Recipient or an optionee, as a condition of receiving Common Shares or exercising an option, to give written assurances in substance and form satisfactory to the Company to the effect that such person is acquiring the Common Shares awarded or subject to the option for his or her own account for investment and not with any present intention of selling or otherwise distributing the same and to such other effects as the Company deems necessary or appropriate in order to comply with applicable federal and state securities laws.

(b) Transfers. A holder of Common Shares shall not make any Transfer, or enter into, consent to or vote in favor of any transaction that would result in any Transfer unless all the provisions of the Plan and the Operating Agreement that are applicable to such Transfer have been complied with.

(c) Failure to meet Obligation to Sell. If a holder of Common Shares becomes obligated to sell any Common Shares to the Company under the Plan and fails to deliver such Common Shares in accordance with the terms of the Plan, the Company may, at its option, in

addition to all other remedies it may have, send to the holder the applicable purchase price for such Common Shares as is herein specified. Thereupon, the Company, upon written notice to the holder, shall reflect the sale of such Common Shares to the Company or its assignee on its books and all of the holder's rights in and to such Common Shares shall terminate.

(d) Compliance with Securities Law. Each grant of Common Shares and each exercise of an option or the issue or purchase of Common Shares under an option shall be subject to the requirement that if, at any time, counsel to the Company shall determine that the registration or qualification of the Common Shares subject to such grant or option under any state or federal law, or the consent or approval of any governmental or regulatory body, or the disclosure of non-public information or the satisfaction of any other condition is necessary as a condition of, or in connection with the issuance or purchase of Common Shares thereunder, such Common Shares shall not be granted and such option shall not be exercised, in whole or in part, unless such registration, qualification, consent or approval or satisfaction of such condition shall have been effected or obtained on conditions acceptable to the Board of Managers. Nothing herein shall be deemed to require the Company to apply for or to obtain such registration or qualification or to satisfy such condition.

6.2. **Adjustment Provisions for Recapitalization, Reorganizations and Related Transactions.**

(a) Recapitalization and Related Transactions. If, through or as a result of any recapitalization, reclassification, distribution, Common Share split, reverse Common Share split, liquidation, exchange of Common Shares, spin-off, combination, consolidation or other similar transaction, (i) the outstanding Common Shares are increased, decreased or exchanged for a different number or kind of Common Shares or other securities of the Company or (ii) additional Common Shares or new or different Common Shares or other non-cash assets are distributed with respect to such Common Shares or other securities, an appropriate and proportionate adjustment shall be made in (x) the maximum number and kind of Common Shares reserved for issuance under the Plan, (y) the number and kind of Unvested Common Shares granted and Common Shares or other securities subject to any then outstanding options under the Plan and (z) the exercise price for each Option Common Share, without changing the aggregate purchase price as to which such options remain exercisable. Notwithstanding the foregoing, no adjustment shall be made pursuant to this Section 6.2 if such adjustment would be considered as the adoption of a new plan requiring member approval.

(b) Reorganization, Merger and Related Transactions. If the Company shall be the surviving company in any reorganization, merger or consolidation of the Company with one or more other entities, any then outstanding options or Unvested Common Shares shall pertain to and apply to the securities, cash and any other assets to which a holder of the number of Common Shares subject to such options or Unvested Common Shares would have been entitled immediately following such reorganization, merger or consolidation, with a corresponding proportionate adjustment of the purchase price as to which such options may be exercised so that the aggregate purchase price as to which such options may be exercised shall be the same as the aggregate purchase price as to which such options may be exercised for the Option Common Shares immediately prior to such reorganization, merger or consolidation.

(c) Board Authority to Make Adjustments. Any adjustments made under this Section 6.2 shall be made by the Board of Managers, whose determination as to what adjustments, if any, shall be made and the extent thereof shall be final, binding and conclusive. No fractional Common Shares shall be issued under the Plan on account of any such adjustments.

6.3. **Change of Control; Acceleration.**

(a) Definition. "Change of Control" shall mean (i) a "Change of Control" as defined in the Operating Agreement; or (ii) a "Deemed Liquidation Event" as defined in the Operating Agreement.

(b) Acceleration of options; Notice. Upon the occurrence of a Change of Control, the Board of Managers may, in its discretion and upon the satisfaction of any such conditions as the Board of Managers may provide, provide that a portion or all options granted by the Company shall accelerate and that a portion or all of the then currently unvested options shall become vested and exercisable immediately prior to the consummation of the Change of Control. To the extent any option that has been accelerated as described in this Section 6.3(b) is not exercised immediately prior to consummation of a Change of Control, the unexercised portion of such option shall terminate in its entirety automatically upon such consummation. Unless the Board of Managers elects to pay optionees the consideration for their options contemplated by Section 6.3(c) or such options are to be assumed or substituted pursuant to Section 6.3(e), the Company shall, no later than five days prior to the date of such consummation, notify optionees who hold options that will be exercisable immediately prior to the consummation of the Change of Control that the unexercised portion of such options will terminate in their entirety automatically upon such consummation.

(c) Consideration and Option Common Shares. Upon the occurrence of a Change of Control, after giving effect to the acceleration provisions of Section 6.3(b), the Board of Managers may, in its sole discretion, pay to the optionees for each vested Option Common Share for which such option is then exercisable (i) the consideration that would have been payable for such Option Common Share pursuant to the Change of Control had such Option Common Share been issued immediately prior to the Change of Control, less (ii) the exercise price for such Option Common Share; provided, however, that if such consideration does not consist entirely of cash, the Board of Managers may reduce the value of such exercise price from such consideration in any manner that the Board of Managers shall determine in good faith. The Board of Managers may, in its sole discretion, provide that the payment of such consideration for each Option Common Share subject to any unvested option being accelerated in accordance with Section 6.3(b) shall be deferred (each, a "Deferred Option Payment") and paid on a date after the consummation of the Change of Control as specified by the Board of Managers (the "Deferred Option Payment Date"), whether or not the optionee remains an employee of the Company on such date. The Board of Managers may, in its sole discretion, authorize payment of any Deferred Option Payment prior to the Deferred Option Payment Date to any optionee who elects to execute a general release in a form provided by the Company prior to the date determined by the Board of Managers in its sole discretion, in which case the Deferred Option Payment shall be payable promptly after the expiration of any period during which such general release may be revoked.

(d) Acceleration of Unvested Common Shares. Upon the occurrence of a Change of Control, the Board of Managers may, in its discretion and upon the satisfaction of any such conditions as the Board of Managers may provide, provide that the restrictions on a portion or all of the then currently Unvested Common Shares shall lapse and shall become unrestricted Common Shares immediately prior to the consummation of the Change of Control.

(e) Assumption or Substitution of Awards. In the event of a Change of Control, any portion of an option that is not accelerated as to vesting or any portion of an Unvested Common Share award as to which restrictions are not deemed lapsed shall be assumed or an equivalent option or right shall be substituted by the successor entity or a parent or an affiliate of such successor entity (such entity, the "Successor Company"), unless the Successor Company does not agree to such assumption or substitution. Any such assumption or substitution of an option shall not result in any increase in the aggregate spread between the Fair Market Value of the Common Shares underlying such option and the exercise price applicable to such option. Any option (or portion thereof) described in this Section 6.3(e) that is neither exercised by the optionee nor assumed by a Successor Company shall terminate automatically upon the consummation of the Change of Control. Any Unvested Common Share award described in this Section 6.3(e) that is not assumed by the Successor Company shall be repurchased by the Company at the price paid by the Recipient upon the consummation of the Change of Control.

(f) Consideration Including Securities. If the consideration to be paid in exchange for the securities of the Company pursuant to a Change of Control includes any securities and due receipt thereof by any Recipient or optionee would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities or (y) the provision to any Recipient or optionee of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Recipient or optionee in lieu thereof, against surrender of such securities which would have otherwise been sold by such Recipient or optionee, an amount in cash equal to the fair value (as determined in good faith by the Board of Managers) of the securities which such Recipient or optionee would otherwise receive as of the date of their issuance in exchange for the securities held by such Recipient or optionee.

6.4. **"Market Stand-Off' Agreement**

No Recipient or optionee shall, without the prior written consent of the managing underwriter (s), during the period commencing on the date of the final prospectus relating to the registration by the Company of any of its equity securities under the Securities Act on a registration statement on Form S-l or Form S-3, or any successor form thereto, and ending on the date specified by the Company and the managing underwriter(s) (such period not to exceed 180 days or such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in Financial Industry Regulatory Authority (FINRA) rules or the rules of any exchange on which the Common Shares (or any securities the Common Shares have been converted to) are then trading, or any successor provisions or amendments thereto), (a) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right or

warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any equity securities of the Company or any securities convertible into or exercisable or exchangeable (directly or indirectly) for any equity securities of the Company held immediately before the effective date of the registration statement for such offering or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of equity or other securities, in cash or otherwise. The foregoing provisions of this Section 6.4 shall not apply to the sale of any equity securities of the Company to an underwriter pursuant to an underwriting agreement, or the transfer of any equity securities of the Company that is made for bona fide estate or tax planning purposes, either during the lifetime of a holder or on death by will or intestacy to his or her family members, or any other person approved by the Board of Managers, or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such holder or any such family members; provided that the holder (or such holder's representative in the case of death) shall deliver prior written notice to the Company of such transfer and such equity securities shall at all times remain subject to the terms and restrictions set forth in the Plan and such transferee shall, as a condition to such transfer, agree to be bound by all the terms and conditions of the Plan (but only with respect to such equity securities) and, provided further, that such transfer is made pursuant to a transaction in which there is no consideration actually paid for such transfer. The underwriters in connection with such registration are intended third-party beneficiaries of this Section 6.4 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Recipient and optionee further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 6.4 or that are necessary to give further effect thereto. The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such market stand-off period. Any attempted Transfer of such securities contrary to the provisions hereof, and the levy of any execution, attachment or similar process upon such securities, shall be null and void and without effect.

6.5. **Drag Along.**

In the event that (x) the Board of Managers and (y) the Required Preferred Holders approve a Sale of the Company in writing, then each Recipient hereby agrees to be bound by Section 7.8 of the Operating Agreement.

6.6. **No Requirement to Continue Business Relationship.**

Nothing contained in the Plan or in any share or option agreement shall confer upon any Recipient or optionee any right with respect to the continuation of the Business Relationship of the Recipient or optionee with the Company or interfere in any way with the right of the Company at any time to terminate or alter the scope of such Business Relationship.

6.7. **Other Employee Benefits.**

Except as to plans which by their terms include such amounts as compensation, the amount of any compensation deemed to be received by an employee as a result of the grant of Common Shares or lapse of restrictions thereon, the exercise of an option or the sale of any Option Common

Shares received upon such exercise shall not constitute compensation with respect to which any other employee benefits of such employee are determined, including, without limitation, benefits under any bonus, pension, profit-sharing, life insurance or salary continuation plan, except as otherwise specifically determined by the Board of Managers.

6.8. **Amendment of the Plan.**

The Board of Managers may at any time, and from time to time, modify or amend the Plan in any respect, except that if at any time the approval of the members of the Company is required, the Board of Managers may not effect such modification or amendment without such approval. Except as provided in the next sentence, no modification or amendment of the Plan shall, without the consent of the optionee or Recipient, as the case may be, adversely affect the rights of an optionee or Recipient under an option or grant of Common Shares previously made. If the Company is converted into a corporation, the Board of Managers may amend the Plan as the Board of Managers deems necessary in order to reflect the conversion of the Common Shares into stock of a corporation and in order to comply with, or avoid any loss of any benefit to the Company or any optionee or Recipient as a result of or obtain any benefit to the Company or any optionee or Recipient under, any law or regulation applicable to the Plan as then amended.

6.9. **Withholding.**

The Company or any of its affiliates, as applicable, shall have the right to deduct from payments of any kind otherwise due to the optionee or Recipient any federal, state or local taxes of any kind required by law to be withheld with respect to any Common Shares issued as unrestricted Common Shares or upon exercise of options or lapse of restrictions on Unvested Common Shares under the Plan. Subject to the prior approval of the Company, which may be withheld by the Company in its discretion, the optionee or Recipient may elect to satisfy such obligations, in whole or in part, (i) by causing the Company to withhold Common Shares otherwise issuable pursuant to the grant of unrestricted Common Shares or exercise of an option or lapse of restrictions on Unvested Common Shares or (ii) by delivering to the Company Common Shares already owned by the optionee or Recipient. The Common Shares so delivered or withheld shall have a Fair Market Value equal to such withholding obligation as of the date that the amount of tax to be withheld is determined. An optionee or Recipient who has made an election pursuant to this Section 6.9 may satisfy such withholding obligation only with Common Shares which are not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

6.10. **Effective Date and Duration of the Plan.**

(a) Effective Date. The Plan shall become effective when adopted by the Board of Managers. Amendments to the Plan not requiring member approval shall, unless otherwise provided by the Board of Managers, become effective when adopted by the Board of Managers. Amendments requiring member approval (as provided in Section 6.8) shall become effective when adopted by the Board of Managers and approved the Company's members to the extent required by the Operating Agreement.

(b) Termination. Unless sooner terminated in accordance with the Plan, the Plan shall terminate upon the earlier of (i) any date determined by the Board of Managers at any time, (ii)

the date on which all Common Shares available for issuance under the Plan shall have been issued and are free of all restrictions hereunder or (iii) the dissolution or liquidation of the Company. If the date of termination is determined under (i) above, then options or Common Shares awarded hereunder outstanding on such date shall continue to have force and effect in accordance with the provisions of the option and share agreements.

6.11. **Waiver of Jury Trial.**

By accepting an option or an award of Common Shares under the Plan, each recipient of options or Common Shares under the Plan waives any right to a trial by jury in any action, proceeding or counterclaim concerning any rights under the Plan and option or share agreement, or under any amendment, waiver, consent, instrument, document or other agreement delivered or which in the future may be delivered in connection therewith, and agrees that any such action, proceedings or counterclaim shall be tried before a court and not before a jury. By accepting an option or an award of Common Shares under the Plan, each recipient of options or Common Shares under the Plan certifies that no officer, representative or attorney of the Company has represented, expressly or otherwise, that the Company would not, in the event of any action, proceeding or counterclaim, seek to enforce the foregoing waivers.

6.12. **Limitation of Liability.**

Notwithstanding anything to the contrary in the Plan, neither the Company, nor any of its affiliates, nor the Board of Managers, nor any person acting on behalf of the Company, any of its affiliates or the Board of Managers, shall be liable to any recipient of options or Common Shares under the Plan or to the estate or beneficiary of any recipient of options or Common Shares under the Plan by reason of any acceleration of income, or any additional tax (including any interest and penalties), asserted by reason of the failure of an option or an award of Common Shares to satisfy the requirements of Section 409A or by reason of Section 4999 of the Code, or otherwise asserted with respect to an award; provided, that nothing in this Section 6.11 shall limit the ability of the Board of Managers or the Company, in its discretion, to provide by separate express written agreement with a recipient of options or Common Shares under the Plan for a gross-up payment or other payment in connection with any such acceleration of income or additional tax.

6.13. **Governing Law.**

The provisions of the Plan shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts of law principles.

6.14. **Pronouns.**

As used in the Plan, all pronouns and any variations thereof refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

6.15. **Legends.**

(a) Securities Laws. All certificates representing Common Shares, and until such time as Common Shares are sold in an offering which is registered under the Securities Act and any applicable state securities law or unless an exemption from such registration is available and the

Company shall have received, at the expense of the holder thereof, evidence of such exemption reasonably satisfactory to the Company (which may include, among other things, an opinion of counsel satisfactory in form and content to the Company that such registration is not required in connection with a resale (or subsequent resale) of the Common Shares), all certificates issued in Transfer thereof or substitution therefor, shall, where applicable, have endorsed thereon the following (or substantially equivalent) legend:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "SECURITIES ACT"), AND HAVE BEEN IS SUED IN RELIANCE ON AN EXEMPTION FROM REGISTRATION PROVIDED FROM REGULATIONS UNDER THE SECURITIES ACT. THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE OFFERED OR SOLD, DIRECTLY OR INDIRECTLY, EXCEPT (A) PURSUANT TO AND IN CONFORMITY WITH (I) AN EFFECTIVE REGISTRATION
>
> STATEMENT UNDER THE SECURITIES ACT OR (II) ANY THEN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS UNDER THE SECURITIES ACT AND (B) PURSUANT TO AND IN CONFORMITY WITH ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS. OTHER THAN PURSUANT TO AND IN CONFORMITY WITH AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT, NO SUCH OFFER OR SALE OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY BE MADE UNLESS, IF REQUESTED BY IT, RALLYBIO HOLDINGS, LLC HAS RECEIVED A WRITTEN LEGAL OPINION OF COUNSEL (SUCH COUNSEL AND OPINION REASONABLY ACCEPTABLE TO IT) TO THE EFFECT THAT SUCH OFFER OR SALE DOES NOT VIOLATE THE SECURITIES ACT OR ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS."

(b) Restrictions. Until the Right of First Refusal has terminated in accordance with the Plan, all certificates representing the Common Shares shall have endorsed thereon the following (or substantially equivalent) legend:

> "THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS SET FORTH IN THE COMPANY'S 2018 SHARE PLAN, A COPY OF WHICH IS AVAILABLE FOR INSPECTION AT THE OFFICES OF THE COMPANY OR SHALL BE MADE AVAILABLE UPON REQUEST."

6.16. **Definitions.**

As used in the Plan, the following terms shall have the respective meanings set forth below or in the Section of the Plan set forth below:

(a) "Beneficial Ownership" shall have the meaning set forth in Section 409A.

(b) "Business Relationship" shall mean serving the Company or any of its affiliates in the capacity of an employee, officer, manager, director, advisor or consultant.

(c) "Change of Control" shall have the meaning set forth in Section 6.3(a) of the Plan.

(d) "Code" shall mean the Internal Revenue Code of 1986, as amended.

(e) "Common Share" shall have the meaning set forth in the Operating Agreement.

(f) "ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended.

(g) "Fair Market Value" shall have the meaning set forth in Article IV of the Plan.

(h) "Operating Agreement" shall mean the Operating Agreement of the Company, dated as of April , 2018, as amended, modified or supplemented from time to time.

(i) "Person" shall have the meaning set forth in Section 409A.

(j) "Required Preferred Holders" shall have the meaning set forth in the Operating Agreement.

(k) "Sale of the Company" shall have the meaning set forth in the Operating Agreement.

(l) "Section 409A" shall mean section 409A of the Code and the regulations promulgated under that section.

(m) "Transfer" shall mean any sale, pledge, assignment, encumbrance, gift or other disposition or transfer by any person or entity of outstanding Common Shares or any legal or beneficial interest therein, including any tender or transfer in connection with any merger, recapitalization, reclassification or tender or exchange offer (for all or part of the outstanding equity of the Company), whether or not the person or entity making such transfer votes for or against any transaction involving any such Transfer.

Adopted by the Board of Managers of the Company on the __ day of _____, 20__.

Adopted by the members of the Company on the __ day of ____, 20__.