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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-40693

RALLYBIO CORPORATION
(Exact name of Registrant as specified in its Charter)

Delaware	**85-1083789**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
234 Church Street New Haven, CT	**06510**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 859-3820

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RLYB	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by checkmark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b) ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the registrant's voting common stock held by non-affiliates as of June 30, 2025 was approximately $10.6 million, based on the closing price of the registrant's common stock as reported by Nasdaq on that date.
The number of shares of Registrant's common stock outstanding as of March 6, 2026 was 5,289,675.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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:

- our proposed Merger (as defined below) with Candid Therapeutics, Inc, a Delaware corporation ("Candid") and any potential benefits of the merger;
- 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 timing of initiation and completion of our clinical trials for RLYB116, and related preparatory work, and the period during which the results of the trials will become available;
- the success, cost and timing of the clinical development of our product candidates, including RLYB116;
- the potential of our product candidates to treat certain target diseases;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- 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 immune platelet transfusion refractoriness and refractory antiphospholipid syndrome;
- our reliance on third parties to conduct our clinical trials;
- enhancements to the manufacturing process for RLYB116;
- our reliance on third parties to manufacture drug substance and drug product for use in our clinical trials;
- our ability to identify and advance through clinical development any additional product candidates;
- our ability to obtain and maintain regulatory designations allowing for priority review of our product candidates, and 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;
- the size and growth potential of the markets for RLYB116 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- 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 from any future offerings;
- the potential benefits of strategic collaboration agreements and arrangements, including our agreement with Johnson & Johnson, and the expected timing of updates related thereto, 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 Jumpstart Our Business Startups Act of 2012;
- 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K. 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.

Trademarks

We use Rallybio as a trademark in the United States ("U.S.") and/or in other countries. This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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.

Risk Factor Summary

Our business is subject to a number of risks that are discussed more fully in the “Risk Factors” section of this Annual Report on Form 10-K. These risks include the following:

- Failure to complete, or delays in completing, the proposed Merger with Candid could materially and adversely affect our results of operations, business, financial results and/or stock price;
- The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry-wide changes and/or other causes;

- Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger;

- We have incurred significant losses since our inception and anticipate that, if we continue to progress the development of our product candidates, 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;

- If we continue to progress the development of our product candidates, we will require significant additional capital to fund our operations. If we continue to progress the development of our product candidates and fail to obtain necessary financing, we may not be able to complete the development or commercialization of RLYB116 or any other product candidate. Given our limited resources and access to capital, we may decide to prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business;

- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates;
- Our failure to meet the listing standards of the Nasdaq Stock Market LLC, ("Nasdaq"), could result in the delisting of our common stock. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue to operate as a going concern would be substantially impaired;

- We are heavily dependent on the success of RLYB116, which is in early-stage clinical development. If we continue to progress the development of our product candidates, and we are not able to develop, obtain marketing approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed;

- Preclinical studies and clinical trials are expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. If we continue to progress the development of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of these product candidates;

- Enrollment and retention of patients in rare disease clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control;

- If we continue to progress the development of our product candidates, 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;

- If we continue to progress the development of our product candidates, 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 marketing approval processes of the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), and comparable foreign regulatory authorities, including the Medicines and Healthcare products Regulatory Agency in the United Kingdom (the “MHRA”), are lengthy, time-consuming, and inherently unpredictable, and if we continue to progress the development of our product candidates and are ultimately unable to obtain marketing approval for RLYB116 or any of our other product candidates, our business will be substantially harmed;

- Our product candidates target rare diseases and conditions, and if we continue to progress the development of our product candidates, the market opportunities for RLYB116 or any of our other

product candidates, if approved, may be smaller than we anticipate. We must be able to successfully identify patients and capture a significant market share to achieve profitability and growth;

- We face significant competition from biotechnology and pharmaceutical companies, and if we continue to progress the development of our product candidates, our operating results will suffer if we fail to compete effectively;

- If we continue to progress the development of our product candidates, we may pursue business development transactions and 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 which may also impact the value of any potential CVR.

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.”

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PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Our lead program, RLYB116, is a differentiated complement component 5 (“C5”) inhibitor with the potential to treat diseases of complement dysregulation. In addition, RLYB332, a long-acting matriptase-2 ("MTP-2") antibody for the treatment of diseases of iron overload, is currently in preclinical development.

Recent Developments

On March 1, 2026, we entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Candid, a clinical-stage biotechnology company advancing a leading portfolio of T-cell engager ("TCE") therapeutics for autoimmune diseases, and Farmington Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Rallybio (“Merger Sub”). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into Candid, with Candid surviving as a wholly owned subsidiary of Rallybio (the “Merger”). The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Concurrently with the execution and delivery of the Merger Agreement, certain investors entered into subscription agreements with Candid, pursuant to which such investors have agreed to purchase, immediately prior to the Merger, shares of Candid common stock representing an aggregate commitment of approximately $505.5 million in the concurrent financing (the “Concurrent Financing”). The shares of Candid common stock that are issued in the Concurrent Financing will be or will have the right to be, respectively, converted into shares of Rallybio Common Stock, par value $0.0001 per share ("Rallybio Common Stock), in the Merger.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the “Effective Time”), (a) each then-outstanding share of common stock or preferred stock of Candid (each such share, a “Candid Share”) (excluding any share described in clauses (b) or (c) below and Candid Shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Rallybio Common Stock equal to the Exchange Ratio as set forth in the Merger Agreement (the “Exchange Ratio”), (b) each Candid Share issued in the Concurrent Financing will be converted into the right to receive a number of shares of Rallybio Common Stock equal to the Concurrent Financing Exchange Ratio as set forth in the Merger Agreement (the “Concurrent Financing Exchange Ratio”), (c) any Candid Shares held as treasury shares or held or owned by Rallybio, Merger Sub or any subsidiary of Rallybio or Candid immediately prior to the Effective Time will be canceled and shall cease to exist, and no consideration shall be delivered in exchange therefor. Each then-outstanding option to purchase Candid Shares will be converted into an option to purchase Rallybio Common Stock, based on the Exchange Ratio and subject to adjustment as set forth in the Merger Agreement.

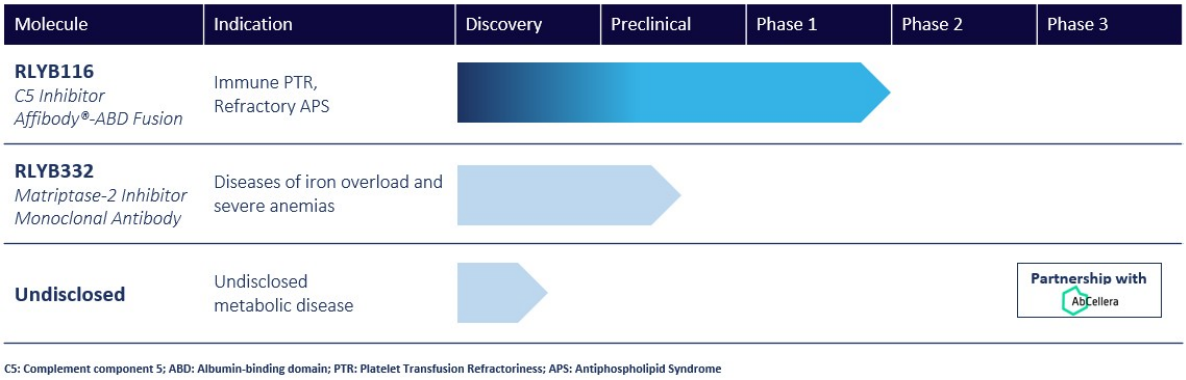
Under the Exchange Ratio and Concurrent Financing Exchange Ratio formulas in the Merger Agreement, immediately after the Closing, on a pro forma basis and based upon the number of shares of Rallybio Common Stock expected to be issued in connection with the Merger, pre-Merger equityholders of Candid (other than investors in the Concurrent Financing) are expected to own approximately 57.55% of the combined company, pre-Merger equityholders of Rallybio are expected to own approximately 3.65% of the combined company and the Investors in the Concurrent Financing are expected to own approximately 38.80% of the combined company (assuming proceeds from the Concurrent Financing of $505.5 million), in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) a valuation for Rallybio of $47.5 million (assuming Rallybio has net cash (“Rallybio Net Cash”) of $37.5 million as of the closing of the Merger (the “Closing” and such date, the “Closing Date”)), (ii) a fixed valuation for Candid of $750.0 million, and (iii) the relative capitalization of Rallybio and Candid. The percentage of the combined company that each party’s equity holders will own following the Closing is subject to certain adjustments as described in the Merger Agreement, including the amount of the final Rallybio Net Cash at Closing.

Immediately prior to the Effective Time, Rallybio and a rights agent are expected to enter into a Contingent Value Rights Agreement (the “CVR Agreement”), pursuant to which holders of record of certain Rallybio securities as of the close of business on the last business day prior to the day on which the Effective Time occurs will receive one contingent value right (each, a “CVR”) for each outstanding share of Rallybio Common Stock, prefunded warrant, Rallybio restricted stock unit or In the Money Parent Option (as defined in the CVR Agreement) held as of such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to receive

their pro rata share of (i) all of the net proceeds (including cash the value of stock to the extent listed on a national exchange, at the time of disposition), if any, received by Rallybio as a result of payments made to Rallybio of any upfront, milestone, royalty and other payments received under any disposition agreement related to Rallybio's pre-Merger assets (the "Legacy Assets"), and (ii) all of the cash proceeds, if any, received from Recursion Pharmaceuticals, Inc. ("Recursion") under the Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion, Exscientia Ventures I, Inc., Rallybio Corporation and Rallybio IPB, LLC. For a period of one year after the Closing Date, Rallybio will use commercially reasonable efforts to effect the disposition of the Legacy Assets. Such net proceeds will be subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred or other liabilities borne by Rallybio or its affiliates in respect of the Legacy Assets, and losses incurred by Rallybio or its affiliates due to a third-party proceeding in connection with such disposition.

Our Pipeline

As part of the proposed Merger with Candid the programs in Rallybio's pipeline that are illustrated in the chart below will be subject to the CVR described above.



C5: Complement component 5; ABD: Albumin-binding domain; PTR: Platelet Transfusion Refractoriness; APS: Antiphospholipid Syndrome

Treatment of Disorders Due to Complement 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 paroxysmal nocturnal hemoglobinuria ("PNH"), atypical hemolytic uremic syndrome ("aHUS"), refractory generalized myasthenia gravis ("gMG") and relapsing neuromyelitis optica spectrum disorder ("NMOSD"). Despite the approval of antibody-based C5 inhibitors for patients with these diseases, we believe there remains a significant need in the market for safe, effective, patient-friendly, and accessible therapies.

Our team has a track record of success in designing, developing, and securing marketing approval for C5 complement inhibitors, including Soliris and Ultomiris, for patients around the world with severe and rare complement-mediated diseases. Our most advanced product candidate in this therapeutic area is RLYB116, an innovative, once-weekly, small volume, subcutaneously injected inhibitor of C5, which is a central component of the terminal complement pathway. RLYB116 is an Affibody molecule attached to an albumin binding domain ("ABD") that has the potential to drive the rapid, complete, and sustained inhibition of C5 with a subcutaneous ("SC") injection. We have completed two Phase 1 clinical trials in healthy participants that included the study of RLYB116 as both a single ascending dose ("SAD") and a multiple ascending dose ("MAD").

After the first Phase 1 clinical trial, we completed manufacturing process enhancements that were designed to improve the tolerability of RLYB116. In 2025, we completed the confirmatory Phase 1 clinical trial evaluating the pharmacokinetic ("PK") / pharmacodynamic ("PD") properties of RLYB116. The confirmatory trial achieved its two key objectives including: a significant improvement in the tolerability of RLYB116 and demonstration of complete and sustained inhibition of terminal complement. These results support the study of RLYB116 as a potential best-in-class therapeutic for multiple complement mediated diseases.

Hematological Disorders

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. In 2024, we re-engineered RLYB331 to extend its half-life. In the fourth quarter of 2024 we presented preclinical data at the annual meeting of the American Society of

Hematology ("ASH") for RLYB332, the long-acting version of RLYB331, including favorable PD data, that support RLYB332 as a long-acting, potentially best-in-class therapy for the treatment of diseases of iron overload. We believe RLYB332 has the potential to address a significant unmet need for patients with severe anemia with ineffective red blood cell production or erythropoiesis and iron overload, such as polycythemia vera, beta thalassemia and a subset of myelodysplastic syndromes ("MDS"), amongst others. Currently these patients are underserved by the existing standard of care.

Artificial Intelligence Drug Discovery Collaboration

In July 2019, we formed a joint venture with Exscientia Limited ("Exscientia"), an Oxford, UK-based artificial intelligence ("AI") and machine learning drug discovery company with a proprietary chemical design platform to discover novel small molecule drug candidates. Exscientia was acquired by Recursion in 2024. In July 2025, we entered into a Membership Interest Purchase Agreement (the “ENPP1 Purchase Agreement”) with Recursion Exscientia Ventures I, Inc., an indirect wholly-owned subsidiary of Recursion (“Buyer”) and Rallybio IPB, LLC, a wholly-owned subsidiary of Rallybio Corporation to sell our interest in REV102, an Ectonucleotide Pyrophosphatase/ Phosphodiesterase 1 ("ENPP1") inhibitor in preclinical development for the treatment of patients with hypophosphatasia ("HPP"), to Buyer (a subsidiary of our joint venture partner Recursion) (the "JV Sale"). In connection with the JV Sale, we received a total of $20.0 million in the third quarter of 2025 including $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. We are eligible to receive a $5.0 million milestone payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by RE Ventures I, LLC ("REV-I"). We may also be eligible to receive certain payments in the event of Recursion’s sale of the REV102 program.

AbCellera Collaboration

In December 2022, we entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration will combine AbCellera Biologic's ("AbCellera") antibody discovery engine with Rallybio’s clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients. We and AbCellera intended that the collaboration would co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies with the first program focused on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Our Strategy

In 2025, the Company made a decision to evaluate strategic alternatives, with a goal of enhancing long term shareholder value that culminated with the signing of the Merger Agreement with Candid, a clinical-stage biotechnology company advancing a leading portfolio of TCE therapeutics for autoimmune diseases on March 1, 2026. In connection with the planned Merger, we have started to take steps to wind down our general and administrative operations that will not be needed after the close of the Merger. We are continuing to move forward with limited research and development operations with a goal of advancing our programs in the near term to maximize the potential value of the CVRs.

Our Product Candidates

RLYB116 for the treatment of disorders due to complement dysregulation

RLYB116 is an inhibitor of complement component C5, a 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. RLYB116 includes an Affibody molecule, which is an antibody mimetic protein that has a much smaller molecular weight than a traditional antibody and may be easier and less costly to produce. In contrast to most C5-targeted antibody therapeutics that are administered intravenously or via daily injection, RLYB116 has the potential to be administered via an autoinjector as a small volume, once-weekly SC injection.

We view RLYB116 as a potential pipeline-in-a-product for many disease including platelet transfusion refractoriness ("PTR") and antiphospholipid syndrome ("APS"). We believe RLYB116 can address significant unmet needs for patients with these diseases by providing a potential treatment that is more accessible and patient-friendly than existing marketed products, including by reducing the frequency and improving the route of administration.

Based on our team's experience studying and developing therapies targeting the complement system, we believe there are five important attributes that could support clinical and commercial success in the treatment of a broad range of patients suffering from complement-mediated diseases. These include a mechanism of action targeting terminal complement, the ability to produce rapid, complete and sustained inhibition of C5, a safety profile consistent with C5 antibodies currently approved for therapeutic use, the ability to self-administer the drug less frequently (e.g. once per week) in an easy to use autoinjector, and pricing flexibility to treat a broad range of complement-mediated diseases. Based on the data generated to date and the manufacturing process enhancements completed in 2024, we believe RLYB116 has the potential to demonstrate these attributes as a best-in-class therapeutic, and if so, could have a life-transforming impact on patients.

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 that converge on C5 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 membrane 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.

Immune platelet transfusion refractoriness (PTR) disease background

PTR is a condition in which a patient shows poor platelet counts after a platelet transfusion due to an immune-mediated process. It can result from antibodies directed against donor platelet antigens—especially human leukocyte antigen ("HLA") class I antigens, or human platelet antigens ("HPAs"). These antibodies rapidly clear transfused platelets from the circulation, leading to transfusion failure. Immune PTR typically develops after prior antigen exposure, such as through previous transfusions. It is diagnosed by consistently low post-transfusion platelet count in the absence of non-immune causes like sepsis or splenomegaly. We estimate that there are more than 25,000 cases annually in the United States and other major markets.

Current treatments for PTR and their limitations

Management of PTR includes using HLA-matched, crossmatched, or HPA-matched platelets, or attempting to address the underlying immune sensitization. Platelet matching, the current standard of care is expensive, challenging and is often not an option in local settings not directly connected to a major blood center. Controlling the immune response is often expensive and is accompanied by a variety of undesirable side effects.

Potential benefits of our approach

We believe PTR represents an attractive development opportunity for RLYB116 for several reasons. First, there are data from at least one investigator initiated trial showing C5 blockade has a positive impact on post-transfusion platelet counts, providing a sound biological rationale for a C5-targeted intervention. Second, PTR offers the opportunity for early clinical validation using objective endpoints, including impact on post-transfusion platelet counts. And third – and most importantly – we believe that RLYB116 could potentially provide transformative therapeutic impact for unserved and underserved patients with PTR globally.

APS disease background

APS is a potentially life-threatening, rare autoimmune disorder in which an individual's immune system mistakenly creates antiphospholipid antibodies that can lead to the formation of blood clots. Blood clots can occur in the legs, lungs, brain, and other organs, such as the kidneys and spleen. The clots can lead to a heart attack or a stroke. During pregnancy, women with APS are also at increased risk of miscarriage. APS can occur on its own but can also occur secondary to other autoimmune diseases such as systemic lupus erythematosus. APS affects three to five times as many women as men and is most often diagnosed in people between the ages of 30 and 50. It is estimated that there are >130,000 people in the US and >120,000 in Europe who suffer from APS.

Current treatments for APS and their limitations

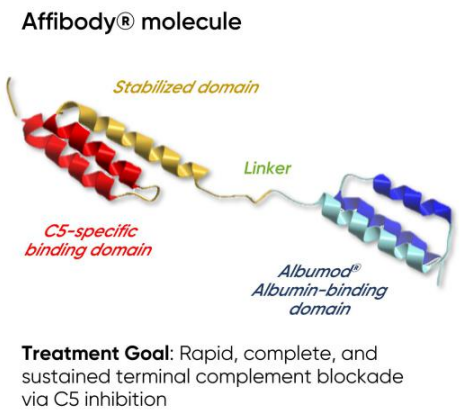
Currently, there is no cure for APS. However, medicines including blood thinners such as warfarin or heparin can help prevent health problems caused by the disease. The goals of treatment are to prevent blood clots from forming and to keep existing clots from increasing in size. However, direct oral anticoagulants are generally less effective in preventing recurrent thromboembolic events, most notably strokes.

Potential benefits of our approach
We believe APS is an attractive indication to pursue as part of a comprehensive development strategy for two reasons. First, there is significant unmet need in patients with APS given the lack of currently available treatment alternatives and the rapid time to generate initial proof-of-concept data. Second, we believe that RLYB116 has the potential to be an effective treatment for this patient population given published data from prior investigational studies using commercially available complement inhibitors not approved in this therapeutic indication.

The RLYB116 solution:
RLYB116 is an engineered protein that includes an Affibody molecule and an antibody binding domain ("ABD"). We acquired rights to RLYB116 from Swedish Orphan Biovitrum AB (Publ) ("Sobi"). RLYB116 was designed for optimal C5 binding, increased stability, as well as a 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 likely enables the delivery of RLYB116 in a patient friendly format such as an autoinjector.
- **Efficiency of manufacturing.** RLYB116 is expressed in E. coli, providing for a more streamlined and potentially lower cost 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 of the Affibody domain to an ABD may lengthen the dosing interval of RLYB116 by extending the biological half-life and offer potential dosing benefits to patients. Based on the data generated to date, we believe that RLYB116 will be administered once-weekly.
- **Potentially lower risk of treatment conversion**. Due to 1:1 binding to C5, there is an expected lack of risk for drug-target-drug 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.

Affibody Scaffold and RLYB116 Structure

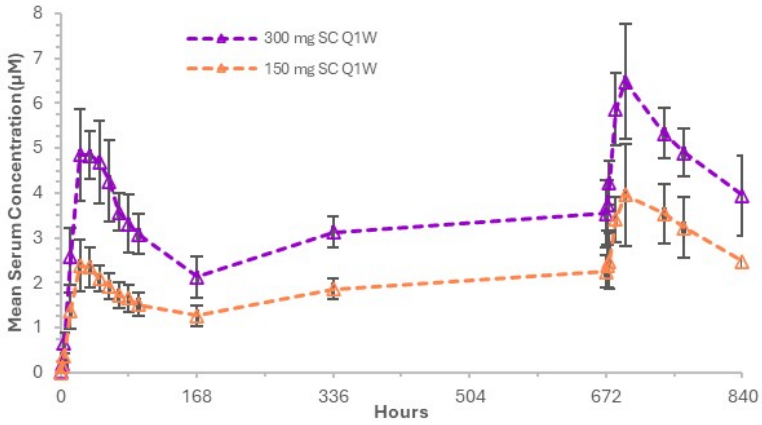


Clinical development of RLYB116
We have completed two Phase 1 clinical trials in healthy participants that included the study of RLYB116 as a SAD and a MAD. After the first Phase 1 clinical trial, we completed manufacturing process enhancements that were designed to improve the tolerability of RLYB116 and enable us to increase the dose.

In 2025, we completed the confirmatory (second) Phase 1 clinical trial evaluating the PK /PD properties of RLYB116 in healthy volunteers. The trial was a single-blind MAD study evaluating a 4-week treatment duration and a 10-week follow-up period. There were eight participants in each of 2 cohorts, six of whom received RLYB116 and two of whom received placebo. The trial is summarized below.

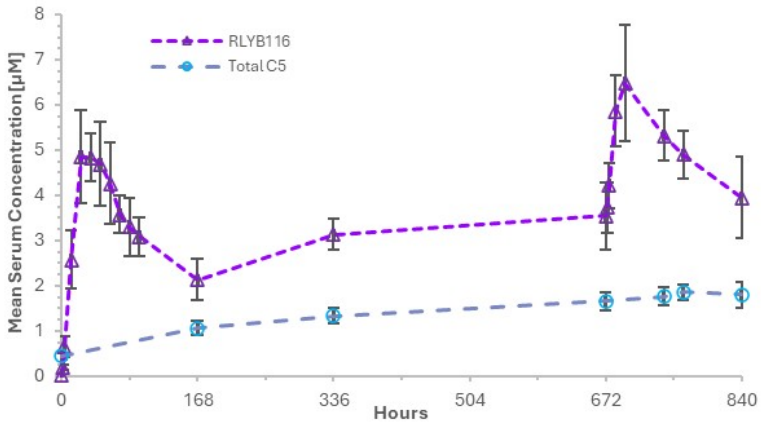
The trial achieved its two key objectives including: a significant improvement in the tolerability of RLYB116 and demonstration of complete and sustained inhibition of terminal complement. We believe the results, which are summarized in the three graphs below, support the study of RLYB116 as a potential best-in-class therapeutic for multiple complement mediated diseases.

Serum RLYB116 Concentration



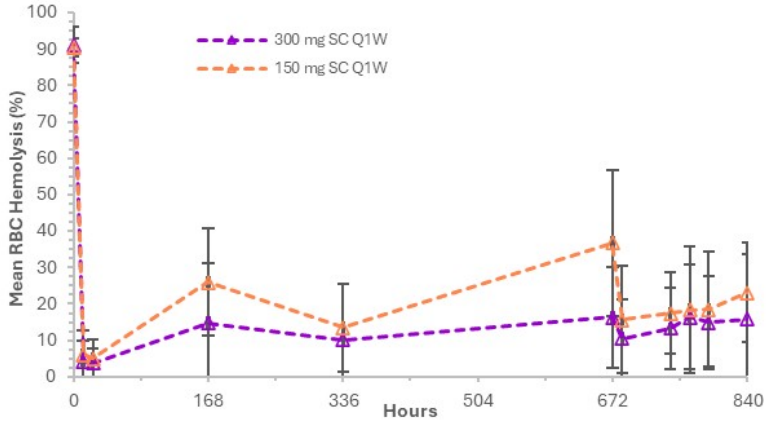
The PK profile of RLYB116 is highly predictable with low intersubject variability, rapid absorption and long terminal elimination rates.

RLYB116 to C5 Ratio



RLYB116 levels significantly exceed C5 within 12 hours of the first dose and are maintained at ratios of greater than 2:1 with a once-weekly, subcutaneously administered dose of 300mg.

Hemolytic Activity



Most importantly, we observed complete and sustained inhibition of hemolysis in subjects who received the 300mg dose.
Based on market research conducted to date, we believe that an effective, once-weekly, well-tolerated therapy that can be rapidly self-administered with an autoinjector would be an attractive alternative for patients suffering from a wide array of complement mediated diseases.

RLYB332 for the treatment of severe anemia with ineffective erythropoiesis and iron overload

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical antibody designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. We believe this molecule has the potential to address a significant unmet need for patients with severe anemias with ineffective erythropoiesis and iron overload, including beta thalassemia and a subset of lower risk MDS. Currently these patients are underserved by the existing standard of care.

In 2024, we completed non-clinical studies that demonstrated favorable tolerability, dose-dependent PK, and sustained PD effects with RLYB332, a long-acting version of RLYB331. These findings, which were presented in a poster at the 66th annual meeting of ASH, support the continued development of RLYB332 as a potentially best-in-class therapeutic for treating diseases of iron overload.

AbCellera Collaboration

We entered into a strategic alliance with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration combines AbCellera's antibody discovery engine with Rallybio's clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients.

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.

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 product 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 ("PTA") which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") 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 ("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 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 1, 2026, we owned two patent families relating to the current product candidates in our complement program, RLYB114 and RLYB116, and certain aspects of their use that were acquired from Sobi. These two patent families currently include five 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. In the United States, Australia, Canada the European Patent Convention contracting states, and Japan, applications in both patent families have been granted and are scheduled to expire between 2033 and 2034, excluding any PTA or PTE. In addition, we filed and own a family of patent applications directed to dosing and administration of RLYB116 that consists of pending patent applications in Australia, Canada, Europe, Japan, the United States and 22 additional countries. Patents issuing in this patent family will have an expiration date in November 2042, excluding any PTA or PTE that may be awarded. We also filed and own nine pending provisional patent applications directed to methods of treatment of various C5-related conditions by administration of RLYB116. We have also non-exclusively 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.

As of March 1, 2026, we exclusively in-licensed from Kymab Limited certain patent rights to the current product candidate in our iron overload program, RLYB332, as well as back-up compounds. Under the exclusive license, we are managing prosecution of a patent family relating to RLYB332 and the back-up compounds. The patent family currently includes pending patent applications in the United States and in more than 20 other countries/regions, including Australia, Brazil, Canada, China, Eurasia, Europe, India, Japan, Mexico, and Saudi Arabia. Patents have been granted in Eurasia, Japan, and Malaysia, and are scheduled to expire in November 2040. In addition, we filed and own a pending International (PCT) patent application family directed to use of RLYB332 for treating pathologies of beta-thalassemia. Further, we have non-exclusively in-licensed from Kymab Limited certain patent rights relating to the development, manufacture, and use of RLYB332 and the back-up compounds.

License Agreements

Product License Agreement with Affibody AB

In March 2019, our subsidiary IPC Research, LLC ("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 ("PLA") as amended, between Sobi and Affibody AB ("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 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 (1) a non-exclusive right under certain patents to use the Affibody ligands alone or as a fusion protein and (2) 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.

Product License Agreement with Sanofi

In May 2022, through our subsidiary, Rallybio IPE, LLC ("Rallybio IPE"), we entered into a License Agreement with Kymab Limited ("Sanofi", and such agreement the "Sanofi License Agreement"). Under the Sanofi License Agreement, Sanofi provides Rallybio IPE with worldwide exclusive rights to Sanofi's KY1066, which is now referred to as RLYB331. Under the terms of the Sanofi License Agreement, Rallybio has an exclusive license to certain Sanofi patents to develop, manufacture and commercialize RLYB331 and Rallybio agrees to use commercially reasonable efforts to develop and commercialize a licensed product in at least one indication in the field in each of several major markets, as described in the Sanofi License Agreement.

We paid Sanofi an upfront cash payment of $3.0 million. In addition, Rallybio has agreed to pay Sanofi up to an aggregate of $43.0 million in development and regulatory milestones and up to an aggregate of $150.0 million in commercial milestones for a product in its first indication, plus tiered low-to-mid double digit percentages of such milestone amounts for up to three additional indications, and mid to high single digit royalties on net sales.

The Sanofi License Agreement contains other customary license terms including sublicensing, development, regulatory, manufacturing, commercialization, milestones, royalties, intellectual property, and termination. The Sanofi License Agreement will expire on a product-by-product and country-by-country basis at the end of the applicable royalty term. Either party may terminate the Sanofi License Agreement upon material breach of the Sanofi License Agreement by the other, subject to a cure period. Rallybio may terminate the Sanofi License Agreement for convenience upon 90 days prior written notice to Sanofi. Sanofi may terminate the Sanofi License Agreement immediately in the case of Rallybio's insolvency, bankruptcy or a similar event, or if Rallybio or its affiliates participates in any proceeding challenging the validity of the licensed patents.

If the Sanofi License Agreement is terminated in its entirety, among other things (a) all rights and licenses granted by Sanofi under the License Agreement (including any sublicenses) will terminate and (b) if Sanofi has an interest in developing, manufacturing and commercializing the licensed compounds or products, the parties to the Sanofi License Agreement shall negotiate an arrangement to provide Sanofi rights to the patents, know-how, materials and other properties controlled by Rallybio applicable to any of the licensed product.

Asset Purchase Agreements

Asset Transfer Agreement with Swedish Orphan Biovitrum AB (Publ)
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, European Union ("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.

Joint Venture Agreement

In July 2019, we entered into a partnership with Recursion (as successor in interest to Exscientia) and created REV-I, which was jointly owned by Recursion and one of our wholly-owned subsidiaries, each a Member and collectively the Members. The joint venture was formed to initiate early-stage drug discovery of orally 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.

In July 2025, we entered into a Membership Interest Purchase Agreement (the “ENPP1 Purchase Agreement”) with Recursion Exscientia Ventures I, Inc., an indirect wholly-owned subsidiary of Recursion (“Buyer”) and Rallybio IPB, LLC, a wholly-owned subsidiary of Rallybio Corporation to sell our interest in REV102, ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Buyer (a subsidiary of our joint venture partner Recursion) (the "JV Sale"). In connection with the JV Sale, we received a total of $20.0 million in the third quarter of 2025 including $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. We are eligible to receive a $5.0 million milestone payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by REV-I. We may also be eligible to receive certain payments in the event of Recursion’s sale of the REV102 program.

AbCellera Collaboration Agreement

In December 2022, the Company entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration combined AbCellera’s antibody discovery engine with Rallybio’s clinical and commercial expertise in rare diseases to identify optimal clinical candidates and ultimately deliver therapies to patients.

Under the terms of the agreement, AbCellera and Rallybio were planning to co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies. The collaboration was designed to allow Rallybio to add product candidates to its existing pipeline and provide the option for AbCellera to conduct process development and clinical manufacturing activities.

Collaboration Agreement with Johnson & Johnson

In April 2024, through Rallybio IPA, we entered into a collaboration agreement (the “J&J Collaboration Agreement”) with Johnson & Johnson, through its wholly-owned subsidiary, Momenta Pharmaceuticals, Inc. (“J&J”). Under the J&J Collaboration Agreement, the Company and J&J planned to advance therapeutic solutions for pregnant individuals at risk of fetal and neonatal alloimmune thrombocytopenia ("FNAIT"). The Company shared certain aggregated, anonymized data with J&J, collected from the Company’s FNAIT natural history study and the Company’s Phase 2 FNAIT clinical trial. The Company also agreed to disseminate information to its FNAIT study sites related to J&J’s and its affiliates’ research and development of complementary therapeutic approaches aimed at reducing the risk of FNAIT.

Under the terms of the J&J Collaboration Agreement, J&J made an upfront payment of $0.5 million. We were also eligible to receive additional payments upon certain triggers related to both companies' FNAIT studies, however, in connection with our decision in April 2025 to discontinue development of RLYB212, we do not expect any payments regarding the achievement of certain enrollment-related events.

The J&J Collaboration Agreement expires in April 2026. The Company may terminate the agreement upon J&J’s material breach, the Company’s decision to discontinue an FNAIT study, or during a certain part of the term if the Company determines for any reason that termination of the agreement is in the best interests of the Company. J&J may terminate the agreement upon the Company’s material, uncured breach, upon the Company’s decision to discontinue an FNAIT study, documented failure of the Company to conduct its FNAIT studies in accordance with applicable law and J&J’s decision to discontinue its FNAIT studies.

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 ("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 plans for 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 ("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 RLYB116 and RLYB332 can be manufactured through reliable and reproducible biologic and chemical processes from readily available starting materials. 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.

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, (the "FDCA"), and in the case of biologics, also under the Public Health Service Act (the "PHSA"), and their implementing regulations. Failure to comply with the applicable U.S. requirements may result in FDA refusal to approve pending New Drug Applications ("NDAs") or Biologics License Applications ("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 an 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 Practice ("GLP") regulations or other applicable regulations;
- manufacture and testing of the therapeutic or biologic moiety and its respective product formulation according to cGMP regulations or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin ;
- approval by an independent institutional review board ("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 ("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;
- 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.

Preclinical Studies and IND

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical development 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. 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, who are commonly healthy volunteers, and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, and if possible, to gain early evidence for effectiveness.
- 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.
- 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.

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.

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 non-clinical 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.

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 ("PDUFA") is substantial (for example, for fiscal year 2025 this application fee is approximately $4.3 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $403,000 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.

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 an 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 cGMPs. 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 Risk Evaluation and Mitigation Strategy ("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 ("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. 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, the FDA may issue either an approval letter or a Complete Response Letter ("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. 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.

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 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 earlier and 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. 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 ("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. The current presidential administration announced in September 2025 that it intends to prioritize enforcement of pharmaceutical advertising requirements.

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 cGMP. 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 Regulation ("QSR") 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 cGMP 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.

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 ("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 ("DSCSA") imposes requirements related to identifying and tracing certain prescription drugs distributed in the United States, including most biological products.

U.S. 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 U.S. patents may be eligible for limited PTE 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 USPTO, in consultation with the FDA, reviews and approves the application for any PTE 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. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("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 ("ACA") was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009 (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. The FDA approved the first interchangeable biosimilar product in 2021 and has since approved others. 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.

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.

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. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the EU, before we may commence clinical trials or market products in those countries or areas.

Until recently, the EMA and the European Commission ("EC") were responsible for approving new medicines for supply in Northern Ireland according to the Northern Ireland Protocol. From January 1, 2025, in accordance with the “Windsor Framework,” all new medicines for the UK market, including Northern Ireland, will be authorized by the MHRA and UK packaging must carry a clearly legible ‘UK only’ to be allowed onto the UK market. The International Recognition Procedure ("IRP") provides the framework for the MHRA to take into account assessments of medicinal products conducted by trusted regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the United States and the EU when assessing applications for marketing authorization.

With the exception of the EU EEA applying harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, and 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 will be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization ("MA") is granted by a competent regulatory agency. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

In the EU, clinical trials are primarily regulated by Regulation (EU) No 536/2014 (the “CTR”).

The CTR requires sponsors to submit one clinical trial authorization (“CTA”) application via the Clinical Trials Information System, which will then be reviewed by the competent regulatory agency selected by the sponsor as the reporting Member State to lead the validation and evaluation of the application. If successful, the resulting CTA would cover all EU Member States concerned by the application. However, a concerned Member State may in limited circumstances declare an “opt-out” from an approval and prevent the clinical trial from being conducted in such Member State. In addition to a CTA, sponsors of clinical trials conducted in the EU must also obtain a positive opinion on the clinical trial from a research ethics committee in each Member State where the trial will be conducted.

Combination Products

Product candidates that incorporate a medical device for the administration of the medicinal product, and which are intended to be commercialized as a single integral product used exclusively in the given combination, will be regulated by Directive 2001/83/EC or Regulation (EC) 726/2004 as a medicinal product. However, the medical device component must satisfy the general safety and performance requirements under applicable EU law governing general medical devices. Proof of such must be included in an application for MA for the combination product. In particular, to the extent the device component has already been conformity assessed and a European Conformity (“CE”) mark affixed, the certificate of conformity issued by the Notified Body must be provided in the MA application dossier. Where the medical device component has not already been CE marked, the MA application dossier must include an opinion issued by a notified body on the conformity of the device component against the relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.

EU regulatory regime contemplates that MAs can be granted either centrally or nationally, albeit through mutual recognition or decentralized procedure, depending on the type of product and the therapeutic indications for which approval is being sought.

Centralized Procedure

The centralized procedure is compulsory for: medicinal products produced by biotechnology; orphan medicinal products; advanced-therapy medicinal products such as gene-therapies; and medicinal products containing new active substances and which are indicated for the treatment of HIV, AIDS and immune dysfunctions, cancer, neurodegenerative diseases, diabetes, autoimmune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for other medicines containing a new active substance, which constitute a significant therapeutic, scientific or technical innovation, or which are in the interest of public health in the EU. Under the centralized procedure, a single MA application is submitted to the EMA where it will be evaluated by its advisory committee, the Committee for Medicinal Products for Human Use (the “CHMP”). Under the centralized procedure, the maximum timeframe for the evaluation of a MA application by the EMA is 210 days, excluding clock stops. Clock-stops allow the applicant the necessary time to provide additional information in response to questions raised by the CHMP. The clock-stops considerably extend the time taken by the CHMP to complete the evaluation of a MA application. The EMA will then provide the EC with an opinion on whether the medicinal product should be approved. Ordinarily, within 67 days of receipt of a positive scientific opinion from the EMA, the EC will adopt single MA an implementing decision on granting a centralized marketing authorization. A centralized MA is valid for all EU member states and, by extension (after taking the corresponding national implementing measures), in Norway, Iceland and Liechtenstein.

National Procedure

The purely national procedure results in a MA in a single EU Member State. This route is available for products not falling within the mandatory scope of the centralized procedure.

Decentralized Procedure

The decentralized procedure allows national MA applications in respect of medicinal products not authorized in the EU/European Economic Area ("EEA") to be submitted simultaneously in multiple EU member states. This is in contrast to the mutual recognition procedure, which applies if the product has been authorized in at least one EU member state on a national basis, and the applicant seeks approval progressively of the same medicinal product in one or more EU member state(s). Both the decentralized and mutual recognition procedures provide for approval by one or more “concerned” member state(s) based on an assessment of an application performed by one “reference” member state. Under the decentralized procedure, an applicant submits an application, accompanied by a dossier, containing the requisite scientific data, and related materials to the reference member state and concerned member state(s). The reference member state prepares a draft assessment and

drafts of the related materials within 120 days of the receipt of a valid application. Within 90 days of receiving the reference member state's positive assessment report, each concerned member state must approve the assessment report and related materials, unless they identify a potential serious risk to public health.

Mutual Recognition Procedure

Under the mutual recognition procedure, the concerned member state(s) have a 90-day period to recognize the MA in the reference member state. The decentralized procedure contemplates a single clock-stop at day 105 for applicants to address questions raised by the reference member state and concerned member states, which may extend the process for completing the assessment procedure.

In either case, if there is a disagreement between member states during the assessment of the submitted data based on concerns about serious risks to public health, the Coordination Group for Mutual Recognition and Decentralized Procedures will consider the matter and seek to reach a conclusion within 60 days. If this is not possible, the reference member state can escalate the issue to the EMA for arbitration.

Conditional Marketing Authorization

In specific circumstances, Regulation (EC) No 726/2004 (as amended) enables applicants to obtain a conditional MA prior to obtaining the comprehensive clinical data required for an application for a full MA. 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 MA 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 MA requires specific obligations to be fulfilled by the MA holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional MAs are valid for one year, and can be renewed annually, if the risk-benefit balance remains positive, and after a satisfactory re-assessment of benefit: risk balance and progress in fulfilling the specific obligations. Failure to submit the required comprehensive data may result in regulatory action against the conditional marketing authorization, including the possibility of its revocation. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional MA.

Pediatric Studies

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan ("PIP"), with the EMA's Pediatric Committee ("PDCO") and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed for the generation of data to support a pediatric indication of the drug for which a MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults or other age groups not covered by the agreed PIP. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO in circumstances where the medicinal product or the product class is likely to be ineffective or unsafe in part or all of the pediatric population; or the disease or condition occurs only in adult populations, or the specific medicinal product does not represent a significant therapeutic benefit over existing treatments in pediatric patients. Products that are granted a MA with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for a six month extension to their supplementary protection certificate. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to the condition that the results are provided in respect of all studies in compliance with the agreed PIP.

European Union Regulatory Data Exclusivity

In the EU, new products containing a new active substance are considered as "reference medicinal products," and accordingly qualify for eight years of data exclusivity and an additional two years of marketing exclusivity upon granting of a MA. 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 medicinal product when applying for a generic or biosimilar MA in the EU. The marketing exclusivity period prevents a successful generic or biosimilar MA applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference medicinal 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 MA 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 it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition, which either (a) affects not more than five in 10,000 persons in the EU when the application is made, or (b) , without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment. In each case, there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized 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 upon grant of a MA, 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 MA 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 MA. The applicant will receive a fee reduction for the MA application if the orphan designation has been granted, but not if the designation is still pending at the time the MA 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, MA 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 of the orphan medicinal product.

An equivalent regime is reflected in domestic law in the UK. Under the UK regime, however, orphan designations are not granted and instead a decision is made at the point of MA grant.

RLYB212 has been granted orphan drug designation by the EMA for the prevention of FNAIT.

Priority Medicines Designation

Developers of innovative medicinal product can apply to the EMA for access to the Priority Medicines ("PRIME") program. A medicinal product will be accepted onto the PRIME scheme if the EMA determines that the available preliminary data demonstrate the medicinal product's 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

In general, an initial MA is valid for five years and may be renewed 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 MA holder must provide the EMA or the competent authority with a consolidated version of the file in respect of the medicinal product's quality, safety and efficacy, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. Once renewed, the MA is generally valid for an unlimited period, unless the EC or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

In accordance with the sunset clause, 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 (in the

case of the national, decentralized and mutual recognition procedures) within three years after the MA is granted will cease to be valid.

The EU is currently revising its general pharmaceutical legislation, known as the ‘Pharma Package’. This initiative is designed to ensure fair access to safe, effective, and affordable medicines throughout the EU. It also aims to boost the competitiveness of the pharmaceutical industry by reducing regulatory burdens and enhancing supply chain security to better prevent and manage shortages.

The legislative process began with the European Commission’s proposal in April 2023, followed by the development of positions by the European Parliament and the Council. Trilogue negotiations concluded with a political agreement in December 2025. The agreed text now awaits formal adoption by both the Parliament and Council, after which it will be published in the Official Journal of the EU.

Key measures include a new exclusivity framework, enhanced incentives for orphan drugs and antibiotics, an expanded Bolar exemption, and a shortened regulatory assessment timeframe. The reforms also introduce stricter controls on product availability and supply shortages. It is anticipated that the new EU pharmaceutical legislation will be fully applicable in 2028, following a two-year transition period.

Additionally, in December 2025, the EC proposed the Biotech Act. This legislation is intended to strengthen the competitiveness of the biotechnology sector and facilitate the development and timely market entry of biotechnology innovations, while maintaining high standards for the protection of human health. The Biotech Act introduces a 12-month extension to the Supplementary Protection Certificate ("SPC") for advanced therapy medicinal products such as gene and cell therapies, and innovative biotech medicines. This extension aims to incentivize EU-based manufacturing and R&D by rewarding novel, highly effective medicines that conduct clinical trials across multiple EU Member States, addressing the time lost in regulatory approval.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU on January 31, 2020, and after the expiry of the transition period on December 31, 2020, became a “third country” for the purposes of EU law. At present, the regulatory regime in the UK broadly aligns with EU regulations. However, it is possible that the regime may diverge in the future. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term.

The EU and the UK concluded a trade and cooperation agreement (“TCA”), which was applied provisionally from January 1, 2021 and entered into force on May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of the outcomes of GMP inspections and GMP documents. However, the TCA does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

To be used or sold in the UK, a medicinal product must have a valid MA granted through the national application process. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the MHRA Submissions Portal. The MHRA operates fixed submission and assessment timetables for innovative medicines applications to facilitate consultation with its statutory advisory committee, the Commission on Human Medicines (“CHM”). The MHRA assessment procedure for a MA application involves an initial evaluation, including orphan designation if applicable, and consultation with expert advisory groups as needed. By Day 90, applicants receive a consolidated request for information (“RFI”), which pauses the review clock until a complete response is submitted electronically. Responses are assessed by Day 150, with further RFIs issued for minor issues or a CHM letter for major objections. Each subsequent RFI requires a complete response within three months, and the clock is restarted upon submission. Applicants may make written or oral representations to the CHM if major objections remain. Final compliance checks are conducted once all issues are resolved, and the MHRA issues a grant or refusal letter specifying any conditions and the MA expiry date. The entire assessment process is designed to be completed within 210 calendar days, excluding any procedural clock-stops for additional information or representations. The innovative medicines timetable allows for a positive decision within 150 clock-on days if all issues are resolved following one round of questions. Where there are outstanding issues at Day 150, we will come to a final decision as soon as possible and within 210 clock-on days. The innovative medicines timetable allows for a positive decision within 150 clock-on days if all issues are resolved following one round of questions. Where there are outstanding issues at Day 150, we will come to a final decision as soon as possible and within 210 clock-on days.

In addition, the MHRA 150-day accelerated review is a specialized, fast-track national MA procedure designed for innovative medicines, new active substances, and biosimilars, aiming for a decision in 150 "clock-on" days rather than the standard 210. It requires high-quality applications, typically involving one round of questions and a 60-day cool-down period for responses.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new IRP for MAAs. The IRP applies from January 1, 2024, and replaces existing EU decision reliance procedure. to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows the MHRA to take into account the assessment and decision-making of the ‘Reference Regulators” to perform a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. There exist two recognition timetables for new IRP MAAs: IRP Route A (60 days) and IRP Route B (110 days), both starting from validation. Eligibility is determined via an applicant-completed form six weeks before submission. Recognition A applies to applications with Reference Regulator approval within the past two years, with no clock stop, but may revert to Recognition B if major objections arise. IRP Route B covers Reference Regulator approvals within the past ten years (or exceptionally older) and applies if specific criteria, such as conditional approvals, manufacturing changes, or UK-specific requirements, are met. IRP Route B allows for consultation with the CHM and aligns with CHM dates for new active substances. Applications not eligible for either timetable may be submitted as full national applications if MHRA requirements are met. IRP can be used for post-authorization measures including line extensions, variations, and renewal application.

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 current good clinical practice 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. Seeking coverage and reimbursement is time consuming and expensive. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, which would be in addition to the studies 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. Coverage and reimbursement varies across third-party payors. 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 a result, we may not be able 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 ("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.

Regulation (EU) 2021/2282 on health technology assessment (the “HTA Regulation”) entered into force on January 11, 2022 and will apply from January 12, 2025. Given the increasing use of HTA to guide market access in EU member states, the HTA Regulation seeks to achieve three legislative objectives: to promote convergence in HTA tools, procedures and methodologies; to ensure efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability. From January 15, 2025, all new oncology medicines and advanced therapy medicinal products (i.e. gene and cell therapies and tissue engineered products) will be assessed at EU level through the Joint Clinical Assessment procedure (“JCA”), which forms part of an HTA and evaluates the relative clinical effectiveness of a new health technology against one or more other health technologies. Importantly, the outcomes of JCAs are not binding on national HTA bodies which may draw their own conclusions on the clinical added value of a new technology. From January 13, 2028, all new orphan medicinal products will be subject to JCA. From January 13, 2030, all new medicines will come under the scope of the HTA Regulation. The HTA Regulation established the Coordination Group on HTA (the “HTACG”) consisting of representatives of EU member states, mainly from HTA authorities or bodies. The HTACG’s remit is to coordinate and adopt the joint HTA work carried out by its subgroups within the scope of the HTA Regulation and to adopt methodological and procedural guidance documents for joint work, including JCAs.

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, which may constrain their business operations. 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 ("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 calculate, report and certify certain complex 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 Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services ("CMS") 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 report information related to payments to health care providers, marketing expenditures or drug prices; state or local laws requiring the registration of pharmaceutical sales representatives; state laws regulating the manufacture and distribution of biopharmaceutical products; 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 U.S. Foreign Corrupt Practices Act of 1977, as amended (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.

Ensuring compliance is time consuming and costly. Violations of the laws may be subject to criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, which could adversely affect our business, financial condition, results of operations, and prospects.

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. Health care reform, specifically reform addressing pricing and payment for drugs, has been an ongoing focus and is likely to continue under the current presidential administration. A number of healthcare reforms involving drugs have been successfully implemented, including reforms related to Medicare payment for drugs and manufacturer rebate obligations under the Medicaid Drug Rebate Program.

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.

For a more detailed discussion of health care reform in the U.S., see “Risk Factors—Risks Related to Healthcare Laws and Other Legal Compliance Matters.”

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, laws requiring notification to governmental authorities and data subjects as well as remediation in the event of a data breach, and laws that afford individuals numerous rights with respect to their personal information.

There have been several developments in recent years with respect to U.S. state data privacy laws. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (collectively, “CCPA”) imposes many requirements for the collection, processing, and sharing of personal information of California residents. The CCPA contains significant penalties for companies that violate its requirements and 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. Several states have proposed or passed comprehensive privacy laws, including several laws imposing obligations similar to those of the CCPA. In addition, several states have proposed or enacted health-focused consumer privacy laws, such as Washington state's My Health, My Data Act, which took effect in March 2024, and imposes obligations related to the collection and sharing of certain health-related information that is not subject to HIPAA and that does not fall within certain other exceptions in the law.

Also of note, in June 2024, the Protecting Americans’ Data from Foreign Adversaries Act of 2024 took effect. This law prohibits data brokers from making available certain personally identifiable sensitive data of U.S. individuals to “foreign adversary” countries, such as the People’s Republic of China (the “PRC”), and entities controlled by such countries. Additionally, in January 2025, the U.S. Department of Justice published a final rule implementing President Biden’s Executive Order 14117, “Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern,” which became effective in April 2025. This final rule prohibits certain data brokerage transactions and transactions involving certain bulk human ‘omic data and biospecimens from which such data can be derived with restricted persons and jurisdictions, such as the PRC, and “covered persons” that have certain ties to such restricted jurisdictions. The final rule also places restrictions on certain vendor, employment and investment agreements with such jurisdictions.

General Data Protection Regulation
Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. For example, 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 General Data Protection Regulation ("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 and imposing strict rules regarding the transfer of personal data to countries outside the EEA, including the United States. The GDPR 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, and 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. 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

As of December 31, 2025, we employed 14 full-time employees. Of our full-time employees, 7 employees are engaged in new product sourcing through business development, research, manufacturing, product development and clinical development, and 7 are engaged in executive, 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.

Corporate Information

Rallybio was founded in 2018. Rallybio Holdings, LLC ("Rallybio Holdings") was formed in Delaware in March 2018 and Rallybio IPD, LLC was formed in Delaware in May 2020. On June 30, 2021, Rallybio IPD, LLC was converted into a Delaware corporation and changed its name to Rallybio Corporation.

Our principal executive offices are located at 234 Church Street, 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 incorporated by reference into this report and you should not consider information contained on or accessible through our website to be part of this report.

Available Information

Our Internet address is https://www.rallybio.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") are available through the “Investors” portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). In addition, our filings with the SEC may be accessed through the SEC’s Interactive Data Electronic Applications system at https://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes appearing in this Annual Report on Form 10-K and the section of this Annual Report on Form 10-K titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” 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. The risks and uncertainties described below are not the only risks 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 “Cautionary Note Regarding Forward-Looking Statements.”

Risks Related to the Merger

Failure to complete, or delays in completing, the proposed Merger with Candid could materially and adversely affect our results of operations, business, financial results and/or stock price.
Any failure to satisfy a required condition to closing may prevent, delay or otherwise materially and adversely affect the completion of the Merger, which could materially and adversely affect our results of operations, business, financial results and/or stock price. We cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that the proposed Merger will be successfully consummated or that we will be able to successfully consummate the proposed Merger as currently contemplated under the Merger Agreement or at all.

Even if certain of the proposals in the Merger Agreement are approved by our stockholders, specified conditions must be satisfied or, to the extent permitted by applicable law, waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived.

Risks related to the failure to consummate, or delay in consummating, the proposed Merger with Candid include, but are not limited to, the following:

- we would not realize any or all of the potential benefits of the Merger, which could have a negative effect on our results of operations, business or stock price;

- under some circumstances, we may be required to pay a termination fee to Candid of $1.425 million, with expense reimbursement of up to $500,000 credited against the payment of any such termination fee;

- we would remain liable for significant transaction costs, including legal, accounting, financial advisory and other costs relating to the Merger regardless of whether the Merger is consummated;
- the trading price of our common stock may decline to the extent that the current market price for our common stock reflects a market assumption that the Merger will be completed;
- the attention of our management and employees may have been diverted to the Merger rather than to our historical operations and the pursuit of other opportunities that could have been beneficial to us;
- we could be subject to litigation related to any failure to complete the Merger;
- we could potentially lose key personnel during the pendency of the Merger; and
- under the Merger Agreement, we are subject to certain customary restrictions on the conduct of our business prior to completing the Merger, which restrictions could adversely affect our ability to conduct our business as we otherwise would have done if we were not subject to these restrictions.

The occurrence of any of these events individually or in combination could materially and adversely affect our results of operations, business, and our common stock price, and we may lose some or all the intended benefits of the Merger.

We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.
Our ability to consummate a strategic transaction depends upon our ability to retain our remaining employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. As of December 31, 2025, we had only 14 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain key personnel that are necessary to maintain our operations between now and the Effective Time. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. Our cash conservation activities may yield other unintended consequences, such as reduced employee morale, which may cause remaining employees to seek alternative employment. The loss of the services of certain employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

The Exchange Ratio will not be adjusted based on the market price of our common stock, so the consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.
The Exchange Ratio will not change based on changes in the trading price of our common stock. Therefore, if before the completion of the Merger, the market price of our common stock increases from the market price on the date of the Merger Agreement, Candid stockholders could then receive merger consideration with substantially higher value for their shares of Candid common stock than the parties had negotiated when they established the Exchange Ratio. The Merger Agreement does not include a price-based termination right. Immediately after the Merger, our securityholders as of immediately prior to the Merger are expected to own approximately 3.65% of the outstanding shares of the combined company and former Candid securityholders, including purchasers in the Concurrent Financing, are expected to own approximately 96.35% of the outstanding shares of the combined company, subject to certain assumptions, including, but not limited to, (a) a valuation of us equal to $47.5 million, based on certain assumptions, including our net cash as of the closing date of the Merger being equal to $37.5 million, (b) a valuation for Candid equal to $750.0 million and (c) Candid issuing approximately $505.5 million of Candid Common Stock in the Concurrent Financing described in the related proxy statement/prospectus.

The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry-wide changes and/or other causes.
In general, either we or Candid can refuse to complete the Merger if there is a Rallybio Material Adverse Effect (as defined in the Merger Agreement) or a Company Material Adverse Effect (as defined in the Merger Agreement), as applicable, between March 1, 2026, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on us or Candid, including:

- general business, political or economic conditions generally affecting the industry in which we or Candid operate, including with respect to the imposition of, or adjustments to, tariffs or other trade restrictions;

- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics and related or associated epidemics, disease outbreaks or quarantine restrictions;

- changes in financial, banking or securities markets;

- any change in the stock price or trading volume of our common stock (it being understood, however, that any effect causing or contributing to any change in stock price or trading volume of our common stock may be taken into account in determining whether a material adverse effect with respect to us has occurred, unless such effects are otherwise excepted from the definition of Rallybio Material Adverse Effect);

- any failure by us to meet internal or analysts' expectations or projections or the results of our operations (it being understood, however, that any effect causing or contributing to the failure of us to meet internal or analysts' expectations or projections or the results of our operations may be taken into account in determining whether a material adverse effect with respect to us has occurred, unless such effects are otherwise excepted from the definition of Rallybio Material Adverse Effect);

- any change in, or any compliance with or action taken for the purpose of complying with, any applicable law or GAAP (or interpretations of any applicable law or GAAP);

- the announcement of the Merger Agreement or the pendency of the Contemplated Transactions; or

- the taking of any action required to be taken by the Merger Agreement.

If a material adverse change occurs with respect to either party or both parties and we and Candid still complete the Merger, the stock price of the combined company following the closing of the Merger may suffer and may reduce the value of the Merger to our stockholders.

Some of our executive officers and directors have interests in the Merger that are different from our stockholders and that may influence them to support or approve the Merger without regard to the interests of our stockholders.
Certain of our executive officers and directors are parties to arrangements that provide them with interests in the Merger that are different from our stockholders, including severance benefits, the acceleration of equity award vesting and continued indemnification.

In addition, Robert Hopfner, a current member of our board, is affiliated with an investment fund participating in the Concurrent Financing.

Our board of directors was aware of and considered these interests, among other matters, in reaching its determination (i) that the terms of the Merger Agreement and the Merger and the other Contemplated Transactions are fair to, advisable and in the best interest of us and our stockholders and (ii) to approve and declare advisable the Merger Agreement and the Contemplated Transactions, including the Merger and the issuance of shares of our common stock to the stockholders of Candid pursuant to the Merger Agreement. These interests, among other factors, may have influenced the directors and executive officers to support or approve the Merger.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.
If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Our equityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.
After the completion of the Merger, our current stockholders will own a smaller percentage of the combined company than their ownership of their respective companies prior to the Merger. Immediately after the Merger, our securityholders as of immediately prior to the Merger are expected to own approximately 3.65% of the

outstanding shares of the combined company and former Candid securityholders, including purchasers in the Concurrent Financing, are expected to own approximately 96.35% of the outstanding shares of the combined company, subject to certain assumptions, including, but not limited to, (a) our valuation equal to $47.5 million, based on certain assumptions, including our net cash as of the closing date of the Merger being equal to $37.5 million, (b) a valuation for Candid equal to $750.0 million and (c) Candid issuing approximately $505.5 million of Candid Common Stock in the Concurrent Financing.

Lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.
Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, Candid, the Candid Board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, Candid, or the Candid board of directors could delay or prevent the Merger, divert the attention of our management and employees from our day-to-day business and otherwise adversely affect our financial condition.

During the pendency of the Merger Agreement, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.
Covenants in the Merger Agreement impede our ability to make acquisitions or complete other mergers, sales of assets or other business combinations pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, knowingly encouraging or entering into specified extraordinary transactions, such as a merger, sale of assets or other business combination, with any third party, subject to specified exceptions, even if any such transaction could be favorable to such party's stockholders or stockholders, as applicable.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.
The terms of the Merger Agreement prohibit each of us and Candid from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in certain limited circumstances. With respect to us, the board of directors may respond to an unsolicited competing proposal if it determines in good faith, after consultation with its outside financial advisor and outside legal counsel, that the unsolicited competing proposal constitutes, or is reasonably likely to result in, a superior competing proposal and, after consultation with its outside legal counsel, that failure to take such action would be inconsistent with the fiduciary duties of our board of directors. With respect to Candid, following receipt of a bona fide acquisition proposal by any person that the Candid Board has determined is reasonably likely to result in a superior competing proposal, Candid may solicit acquisition proposals and furnish information to, and enter into discussions with, any person (including persons not making such proposal) if the Candid Board concludes in good faith, after consultation with its outside legal counsel and financial advisor, that failure to take such action would be inconsistent with the fiduciary duties of the Candid Board.

In certain circumstances, and subject to compliance with the Merger Agreement, our board of directors or the Candid Board may change its recommendation to its respective stockholders if it determines such recommendation change is required to avoid a breach of its fiduciary duties. Additionally, subject to compliance with the procedures set forth in the Merger Agreement, including paying the applicable termination fee, Candid may terminate the Merger Agreement in order to enter into an agreement with respect to a Superior Offer (as defined in the Merger Agreement).

Upon termination of the Merger Agreement in certain circumstances, a termination fee of $1.425 million may be payable by us to Candid if (i) (a) the Merger Agreement is terminated because the Merger has not been consummated by the End Date or we (1) fail to obtain the requisite stockholder approval of the Rallybio Stockholder Matters or (2) breach the Merger Agreement, (b) an alternative acquisition proposal was announced or disclosed prior to such termination, and (c) within 12 months of the termination of the Merger Agreement, we enter into a definitive agreement with respect to an alternative transaction, (ii) we fail to include our board recommendation in the related proxy statement/prospectus, or (iii) our board of directors changes or withdraws its recommendation in favor of the Merger or approves an alternative transaction, or willfully and intentionally breaches its non-solicitation or certain other obligations under the Merger Agreement.

Both we and Candid have also each agreed to reimburse the other party for up to $500,000 for third-party expenses, as applicable, if the Merger Agreement is terminated in certain circumstances.

These termination fees and expense reimbursement provisions may discourage third parties from submitting competing proposals to us or Candid or their respective stockholders and may cause our board of directors or the Candid board, as the case may be, to be less inclined to recommend a competing proposal.

If the Merger does not qualify as a reorganization under the Code, U.S. holders of our Common Stock may be taxed on the full amount of the consideration received in the Merger.
Each of we and Candid intend that the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code. Assuming the Merger so qualifies, no gain will be recognized by U.S. holders of Candid shares will not recognize gain or loss for U.S. federal income tax purposes upon the receipt of shares of our common stock in exchange for Candid shares in the Merger. It is not, however, a condition to the parties' obligation to complete the transactions that the Merger so qualifies. None of the parties to the Merger Agreement have sought or intend to seek any ruling from the Internal Revenue Service ("IRS") regarding the qualification of the Merger as a reorganization within the meaning of Section 368(a) of the Code. If the Merger does not qualify for the U.S. federal income tax treatment described herein, U.S. holders of Candid shares may be taxed on any gain realized up to the full fair market value of any our Common Stock received in the Merger.

We or Candid may waive one or more of the conditions to the Merger without recirculation of the related proxy statement/prospectus or resoliciting stockholder approval.
Conditions to our or Candid's obligations to complete the Merger may be waived, in whole or in part, to the extent permitted by law, in certain circumstances unilaterally or by agreement of us and Candid. In the event of a waiver of a condition, our board of directors will evaluate the materiality of any such waiver to determine whether amendment of the related proxy statement/prospectus and re-solicitation of stockholder approval is necessary.

In the event that our board of directors, in its own reasonable discretion, determines any such waiver is not significant enough to require recirculation of the related proxy statement/prospectus and re-solicitation of its stockholders, it will have the discretion to complete the Merger without seeking further stockholder approval, which decision may have a material adverse effect on our stockholders. For example, if we and Candid agree to waive the requirement that the shares of our Common Stock to be issued in the Merger have been approved for listing (subject to official notice of issuance) on Nasdaq as of the closing of the Merger, and their respective boards of directors elect to proceed with the closing of the Merger, Nasdaq may notify the combined company of its determination to delist the combined company's securities based upon the failure to satisfy the initial inclusion criteria in the Nasdaq application. The combined company may appeal the determination to a hearings panel but such appeal will not stay the suspension and delisting action and Nasdaq may notify the combined company that its common stock will be immediately suspended from trading and delisted.

In addition, in order to meet the initial listing requirements of Nasdaq or as otherwise determined in the discretion of the combined company board pursuant to the terms of the Lock-Up Agreements, our board of directors or combined company board may release stockholders from their Lock-Up Agreements and waive the requirement that such Lock-Up Agreements be in full force and effect immediately following the Effective Time. Such release would increase the number of shares that may be sold in the public market immediately after the Merger and any such sales could cause the combined company's stock price to decline.

Our winddown of our historical operations, the sale of assets, the suspension of development activities and the proposed Merger, resulting in the conversion of Candid into a public company, will make us subject to the SEC requirements applicable to reporting shell company business combinations. As a result, the combined company will be subject to more stringent reporting requirements, offering limitations and resale restrictions.
According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. As such, our plan to merge with Candid, resulting in the conversion of Candid into a public company, will be subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- the combined company will need to file a Current Report on Form 8-K to report the Form 10 type information ("Super 8-K") after closing of the Merger reflecting its status as an entity that is not a shell company;

- the combined company will not be eligible to use a Form S-3 until 12 full calendar months after closing of the Merger;
- the combined company will need to wait at least 60 calendar days after the filing of the Super 8-K to file a Form S-8 for any equity plans or awards, such as the 2026 Plan and the 2026 ESPP;
- the combined company will be an "ineligible issuer" for three years following the closing of the Merger, which will prevent the combined company from (i) incorporating by reference in its Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer ("WKSI") status, even if otherwise eligible based on its public float;
- investors who (i) were affiliates of Candid at the time the Merger was submitted for the vote or consent of Candid's stockholders, (ii) receive securities of the combined company in the Merger and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore would be underwriters with respect to resales of those securities; and
- Rule 144(i)(2) will limit the ability of holders of restricted securities, the investors in the Concurrent Financing, and any affiliates of the public company to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of the combined company per Rule 144, until one year after the Form 10 information is filed with the SEC. Our non-affiliate stockholders prior to the Merger will not be subject to such restrictions on public resales of their shares.

The foregoing SEC requirements will increase the combined company's time and cost of raising capital, offering stock under equity plans, and complying with securities laws. Furthermore, such requirements will add burdensome restrictions on the resale of the combined company common stock by affiliates of Candid and any holders of "restricted" or "control" securities of the combined company.

Our stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

The right of our stockholders to receive any future payment for or derive any value from the CVRs will be contingent solely upon (i) our and Candid's (or the combined company's) ability to monetize all or any part of the Legacy Assets (as defined below) pursuant to one or more disposition agreements entered into within the time period specified in the CVR Agreement, and the timing and amount of the consideration received thereunder and (ii) the receipt of cash proceeds from Recursion Pharmaceuticals, Inc. ("Recursion") under the Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion Pharmaceuticals, Inc., Exscientia Ventures I, Inc., Rallybio and Rallybio IPB, LLC (the "Membership Interest Purchase Agreement"). If we and/or Candid or the combined company (x) are not successful in entering into disposition agreements related to the Legacy Assets (as defined below) or receiving payments thereunder, or if such payments are not sufficient to result in the payment of any our CVR Payments as a result of permitted deductions thereto and (y) do not receive cash proceeds from Recursion pursuant to the Membership Interest Purchase Agreement, in each case within the time period specified in the CVR Agreement, no payments will be made in respect of the CVRs, and the CVRs will expire valueless.

Following the effective time, the combined company will have sole authority over whether and how to monetize the Legacy Assets (if at all), and the combined company's only obligations will be to carry out the obligations set forth in the CVR Agreement.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs and all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company.

The tax treatment of the CVRs is uncertain.
We intend to treat a holder's receipt of the CVRs as a distribution of property with respect to the holder's existing shares of our common stock for U.S. federal income tax purposes, which could be taxable to our stockholders without the corresponding receipt of cash. However, the U.S. federal income tax treatment of the CVRs is uncertain. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments under, the CVRs, and there can be no assurance that the IRS would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

If the Merger is not completed, our stock price may decline significantly.
The market price of our Common Stock is subject to significant fluctuations. During the 12-month period ended March 1, 2026, the closing per share sales price of our Common Stock on Nasdaq ranged from a high of $7.54 on February 27, 2026 to a low of $2.00 (after giving effect to our 1-for-8 reverse stock split approved by our stockholders on January 26, 2026 at a Special Meeting of Stockholders and effective as of 12:01 Eastern Time on February 6, 2026) on April 8, 2025. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our Common Stock will likely be volatile based on whether stockholders and other investors believe that we can complete the Merger or otherwise raise additional capital to support our operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our Common Stock is exacerbated by low trading volume.

Additional factors that may cause the market price of our Common Stock to fluctuate include:

- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the loss of key employees;
- future sales of our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our Common Stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

If we do not complete the Merger, we may face substantial competition for attractive counterparties for any proposed strategic transactions.
There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue an alternative strategic transaction. We may face substantial competition for attractive counterparties for any proposed strategic transactions. For example, there may be many other biotechnology and pharmaceutical companies that halt development of their programs and instead choose to pursue strategic transactions like the ones we have been exploring in connection with our strategic review process. These companies may possess greater financial and managerial resources than we do, and they may have more attractive product candidates, intellectual property or other assets. As a result, these other companies may prove to be more attractive than us to counterparties pursuing strategic transactions. There can be no assurance that any future strategic review process will result in us pursuing a transaction, or that any transaction, if pursued, will be completed on terms favorable to us and our stockholders.

If we do not successfully consummate the Merger or another strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, as to which we can give you no assurance.
There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while pursuing the Merger. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to stockholders. Our

commitments and contingent liabilities may include obligations under our employment and related agreements or policies with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of the company, litigation against us, and other various claims and legal actions arising in the ordinary course of business, and other unexpected and/or contingent liabilities. As a result of this requirement, a portion of our assets would need to be reserved pending the resolution of such obligations.

In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were to be pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company. A liquidation would be a lengthy and uncertain process with no assurance of any value ever being returned to our stockholders.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that, if we continue to progress the development of our product candidates, 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 we have incurred significant operating losses since inception, including net losses of $9.0 million and $57.8 million for the years ended December 31, 2025 and 2024, respectively. Our loss for the year ended December 31, 2025 included a $23.0 million gain in connection with the JV Sale in 2025. As of December 31, 2025, we had an accumulated deficit of $302.0 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, conducting discovery and research activities, acquiring product candidates, establishing and protecting our intellectual property, preparing for and conducting clinical trials, and establishing arrangements with third parties for the manufacture of our product candidates. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

If we continue to progress the development of our product candidates, we expect to incur significant additional operating losses in the foreseeable future as we advance our programs and operate our business. The costs of advancing product candidates through each clinical phase tend to increase substantially over the duration of the clinical development process. The total costs to advance a single 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 generate revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will increase substantially if and as we:

- plan for and conduct any future clinical trials for any of our product candidates, including the ongoing RLYB116 confirmatory clinical PK/PD trial;
- seek regulatory approvals for RLYB116 and any other product candidates;
- advance our discovery and preclinical development activities for our product candidates;
- discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate clinical and commercial quantities of our product candidates; and

- establish a sales, marketing, and distribution infrastructure to commercialize our products, if approved.

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 clinical and commercial manufacturing supply, the building of a commercial organization, and substantial investment before we generate any revenue from product sales. As a result, if we continue to progress the development of our product candidates, 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 RLYB116 or any of our other product candidates, we may continue to incur substantial research and development and other expenses to develop other current or future 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 the 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.

If we continue to progress the development of our product candidates, we will require significant additional capital to fund our operations. If we continue to progress the development of our product candidates and fail to obtain necessary financing, we may not be able to complete the development or commercialization of RLYB116 or any other product candidate. Given our limited resources and access to capital, we may decide to prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business.

If we continue to progress the development of our product candidates, we expect to spend significant amounts of capital to complete the development of, and if approved, commercialize, one or more product candidates, including RLYB116. We are obligated to make certain payments under our agreements with Affibody, Sobi, and Kymab Limited ("Sanofi"), including milestone and royalty payments in connection with achievement of certain development and commercial milestones as well as the sale of resulting products under such agreements. We may also spend significant capital to develop laboratory tests to identify patients for inclusion in our clinical trials or who are likely to respond to our product candidates.

If we continue to progress the development of our product candidates, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2025, will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months beyond the date of the filing of this Annual Report on Form 10-K. This estimate and our expectation to advance the preclinical and clinical development of RLYB116 and any other product candidates are based on assumptions that may prove to be wrong, or we may be subject to changing circumstances. We could exhaust our available capital resources sooner than we expect. Our business is subject to numerous risks and uncertainties, and we may be unable to accurately estimate the actual amount of funds we will require for development and commercialization of our product candidates. 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;

- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities, including any regulatory designations allowing for priority review and 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 RLYB116 and any other product candidates;

- the cost and timing of the manufacture and supply of non-clinical, clinical and commercial quantities of RLYB116 and our other product candidates;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- 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;
- the cost of making royalty, milestone or other payments under our current or any future in-license agreements;
- our ability to maintain our collaboration with AbCellera on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies; and
- the costs of operating as a public company.

If we continue to progress the development of our product candidates, we will require significant additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements, 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 favorable terms, or at all. Furthermore, pursuant to Instruction I.B.6, a company with a public float of less than $75 million measured at certain time periods may not issue securities under Registration Statements on Form S-3 in excess of one-third of its public float in a 12-month period. For purposes of the prior sentence, “public float” means the aggregate market value of a company’s shares held by non-affiliates. We are subject to the limitations of Instruction I.B.6 which may limit the amount of funds we can raise using Registration Statements on Form S-3. Moreover, uncertain geopolitical events, such as the war in Ukraine and conflict in Israel, and uncertain global economic conditions, including as a result of changes in tariffs and other trade restrictions, have impacted the global economy, and a severe or prolonged economic downturn 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 favorable 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, or 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.

Because we have limited financial resources, we have focused and may continue to focus on a limited set of research programs and product candidates and for a limited set of indications. We may forego or delay pursuit of opportunities with certain other product candidates or for other indications that could have greater commercial potential or a greater likelihood of success. Our capital allocation decisions may cause us to fail to realize value from, or advance, viable commercial products or profitable market opportunities.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates.

If we continue to progress the development of our 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, 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, including sales of our common stock pursuant to the Sales Agreement with TD Securities (USA) LLC, each shareholder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their 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 licensing arrangements with third parties, we may be required to relinquish valuable rights to our 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 development or future commercialization efforts for one or more of our product candidates.

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.

Rallybio was founded in January 2018 and our operations to date have been limited primarily to research and development activities, and raising capital. We have not yet demonstrated the ability to successfully complete 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 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 and commercializing pharmaceutical products.

As a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we continue to progress the development of our product candidates, 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 Annual Report on Form 10-K:

- variations in the level of expense related to any ongoing development of our product candidates or research pipeline;
- delays or failures in advancement of any 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;
- if we continue to progress the development of our product candidates, 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;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- potential advantages that our competitors and potential competitors may have in developing and commercializing competing products, securing funding for or obtaining the rights to critical intellectual property;
- regulatory developments affecting our product candidates or those of our competitors;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain and maintain patent protection for our product candidates;
- business interruptions such as power outages, strikes, civil unrest, wars, acts of terrorism or natural disasters; and
- our ability to use our net operating loss ("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 and can be used 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. The deduction for NOLs arising in taxable years beginning after December 31, 2017 is generally limited to 80% of current year taxable income. We also have substantial federal and state research and development and other tax credit carryforwards. 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, (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. Some of our historical NOLs may be subject to annual limitations on our ability to use them due to prior ownership changes. Additionally, we may experience such ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we undergo an ownership change, 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, Marketing Approval and Commercialization

We are heavily dependent on the success of RLYB116, which is in early-stage clinical development. If we continue to progress the development of our product candidates, and we are not able to develop,

obtain marketing 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 program, RLYB116, is in early-stage clinical development and we do not currently have any 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 RLYB212 and RLYB116. If we continue to progress the development of our product candidates, our future success is substantially dependent on our ability to successfully complete preclinical and clinical development for, obtain marketing approval for, and successfully commercialize, RLYB116 and our other product candidates, which may never occur. None of our product candidates are approved for commercial sale and we may never be able to develop a marketable product.

Before obtaining marketing approvals for the commercial sale of our product candidates, we must demonstrate the safety and efficacy of our 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. 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. If we continue to progress the development of our product candidates, 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 marketing approvals. For example, PK data from the Phase 2 clinical trial for RLYB212 demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. There can be no assurance that any of our product candidates, even if approved, will prove to be commercially viable therapeutics.

RLYB116 is designed for SC self-administration. The formulation or physical properties of RLYB116 may ultimately be determined to be inadequate to support this route of administration. If SC administration is not feasible, then we may need to identify additional formulations or routes of administration, which could delay initiation of our future 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.

If we continue to progress the development of our product candidates, the success of our 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 investigational new drug applications 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;
- our ability to successfully utilize certain delivery systems, such as pre-filled syringes ("PFSs"), pen-injectors and/or autoinjectors, for certain of our product candidates and to obtain marketing 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 and commercial supply;
- 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;
- 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 successfully address 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, which would materially harm our business. Due to the uncertain and time-consuming clinical development and marketing 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 prior to receiving marketing approval. 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, or if such product candidates do not achieve the necessary efficacy at tolerated doses required for patient benefit. For example, we discontinued RLYB212 development based on PK data from the Phase 2 clinical trial that demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. 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.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. 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, our business could be materially harmed.

Preclinical studies and clinical trials are expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. If we continue to progress the development of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development 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 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.

If we continue to progress the development of our product candidates, we may experience events that could delay or prevent our ability to complete current clinical trials or initiate and complete new trials, any of which may impact our product development timelines, result in increased costs, affect our ability to obtain marketing approval according to our plans, and delay commercialization of 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 participants and clinical trial sites in sufficient numbers to participate in clinical trials;
- delays in reaching an agreement on acceptable terms with prospective 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 an independent IRB approval at each site within the United States, or Independent Ethics Committee ("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 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;
- 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, we could 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 ("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."

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.

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 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.

If we continue to progress the development of our product candidates, 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. 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 have completed Phase 1 clinical studies for RLYB116, however, 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.

Similarly, 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 trials are subject to additional audit and verification procedures and following such procedures, such interim data could be materially different from the final data.

Enrollment and retention of patients in rare disease clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
If we continue to progress the development of our product candidates, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We currently are conducting, clinical trials with our product candidates in rare disease indications, which can make completion of such trial more difficult. 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 marketing approval or termination of clinical 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 that may limit patients, principal investigators or staff, or clinical site availability.

Additionally, we may have difficulty identifying and enrolling patients for any 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. Our clinical trials for RLYB116 may compete with other clinical trials for product candidates that are being tested for the same indications. 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, 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.

If we continue to progress the development of our product candidates, 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 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 of RLYB116. 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 marketing 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 marketing approval processes of the FDA, EMA and comparable foreign regulatory authorities, including the MHRA, are lengthy, time- consuming and inherently unpredictable, and if we continue to progress the development of our product candidates, and are ultimately unable to obtain marketing approval for 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 Biologics License Application ("BLA") or a New Drug Application ("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. 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. 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 marketing 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 marketing 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 marketing approval for any product candidate and it is possible that we will never obtain marketing 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.

If we continue to progress the development of our product candidates, the FDA, EMA or other comparable foreign regulatory authority can delay, limit, or deny approval of 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;
- 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 policies, regulations, and guidelines of the FDA, EMA or other comparable foreign regulatory authorities regarding the development, approval, and marketing of drugs and biologics may significantly change, including but not limited to, in the U.S., as a result of the 2025 change in presidential administration, which may render our clinical data insufficient for approval or restrict us from marketing our product candidates in the manner in which we anticipate.

We have never obtained marketing approval for a product candidate. If we continue to progress the development of our product candidates, 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 if we continue to progress the development of our product candidates, the market opportunities for RLYB116 or any of our other product candidates, if approved, may be smaller than we anticipate. 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. With respect to RLYB116, we estimate that there are approximately 8,000 patients with immune PTR and up to 10,000 patients with refractory APS 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 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 limited screening or diagnostic tests for the indications our product candidates are being developed to potentially treat. 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.

We face significant competition from biotechnology and pharmaceutical companies, and if we continue to progress the development of our product candidates, 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. If we successfully develop and, if approved, commercialize RLYB116, this therapy may compete with anticoagulants such as Warfarin, or potentially be used in conjunction, with currently marketed treatments and any new therapies that may become available in the future.

If we continue to progress the development of our product candidates, 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, if we continue to progress the development of our product candidates, 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, in recent years, including for 43 days beginning on October 1, 2025 and 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. The Trump Administration has reduced the number of employees serving in government agencies, including the FDA. If a prolonged government shutdown occurs, or if the U.S. government takes other personnel actions, 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.

Even if we obtain marketing 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 marketing 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. 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 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 the FDA's current cGMP requirements regarding the distribution of samples to physicians and recordkeeping and Good Laboratory Practice ("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 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 RLYB116, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize RLYB116. 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 RLYB116. Furthermore, if any confirmatory post-marketing trial fails to confirm the clinical profile or clinical benefits of 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.

If we continue to progress the development of our product candidates, 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 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 and 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.

If we continue to progress the development of our product candidates, we also may seek a Breakthrough Therapy designation for some of our 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 a product candidate 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 a product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that such product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the 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 MA 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 MA 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 HTA 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.

If we continue to progress the development of our product candidates, 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 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 EC 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. We may seek orphan drug designation in the United States and the EU for certain of our 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 MA 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.

If we continue to progress the development of our product candidates, 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 a BLA 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.

If we continue to progress the development of our product candidates, 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 ability to market those products and decrease our or our ability to generate revenue.

If any product candidate is approved for marketing, coverage and reimbursement for such product by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, and other third-party payors would be essential for most patients to be able to afford the prescription medication. Our ability to achieve acceptable levels of coverage and reimbursement for products or procedures using our products 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 and 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, such payors 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 related administration procedures, 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 product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product.

We may also need to provide discounts to purchasers to encourage purchasing of any approved product and rebates to third party payors to increase the possibility of favorable coverage and adequate cost sharing thresholds for patients. We may be required to provide discounts or rebates on any approved product under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal health care programs such as Medicaid. Participation in such programs would require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

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. And, even if products are covered, third party payors may implement various mechanisms to control utilization (e.g., requiring prior approval for coverage for each patient). Additionally, coverage and reimbursement for screening and diagnostic tests

associated with any products would be assessed and determined separately. 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 coverage or 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 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 are able to charge for our products. Accordingly, in markets outside of the United States, the reimbursement for products we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we continue to progress the development of our product candidates, 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. 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 BPCIA was enacted as part of 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, a 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. 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 we continue to progress the development of our product candidates, and 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.

Under the current presidential administration, we face uncertainty regarding potential regulatory developments that may adversely affect our business if we continue to progress the development of our product candidates.

There have been significant and wide-ranging changes in law, regulation and policy under the current Trump administration. Current and future adopt legislation, regulation, or policy could adversely affect our business or creates a more challenging and costly environment to pursue the development and commercialization of our current or future product candidates. For example, the federal government, including the FDA, may implement legislative, regulatory, or policy changes regarding the standards for approving biologic products that we may be unable to satisfy or regarding the marketing of approved biologics that may limit or prohibit the advertising and promotion of our current or future product candidates, if approved. Additionally, the Trump administration has undertaken significant efforts to reduce the size and spending of the federal government, including at the FDA. A significant reduction in the FDA's workforce or the FDA's budget or other disruptions at the FDA could impact the FDA's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. It is difficult to predict how executive actions that may be taken under the current Trump administration may affect the FDA's ability to exercise its regulatory authority. If such executive actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted.

Risks Related to Our Dependence on Third Parties

If we continue to progress the development of our product candidates, we may pursue business development transactions and 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 or out-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our 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 RLYB116 and RLYB114 from Sobi in 2019. We also obtained worldwide exclusive rights to RLYB332 from Sanofi in 2022. If we continue to progress the development of our product candidates, we may 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 relationship 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 product 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 December 31, 2025, we had 14 full-time employees, upon whom we rely for various administrative, research and development, business development and other support services shared among our subsidiaries. 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, 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 and vendors, 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 various laws, including: (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. 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 such as 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, could also 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 and drug product for our preclinical studies and clinical trials and, if we continue to progress the development of our product candidates, expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. 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 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 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.

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 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. 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.

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.

If we continue to progress the development of our product candidates, we 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 CRO 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

If we continue to progress the development of our product candidates, 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. As an earlier example with longstanding impact, 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 eligibility 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 implemented changes to the coverage and reimbursement of drug products under government healthcare programs, including an expansion in the Medicaid drug rebate program, an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid drug rebate program, and the establishment of a new Medicare Part D coverage gap discount program.

Beyond the ACA, there have been ongoing healthcare reform efforts, including efforts focused on drug pricing and payment. For example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs taking effect in 2026). The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Additionally, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap. And changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

Recently, drug pricing and payment has been subject to a number of reform initiatives. For example, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government that is anticipated to offer pharmaceutical direct-to-consumer channels in the future has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured.

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.

Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty.

Other recent government actions may also affect prices or payments for prescription drugs. For example, the Trump Administration's recently announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2032 unless additional Congressional action is taken. 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.

Healthcare or other reform initiatives 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 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.

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.

If we continue to progress the development of our product candidates, 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. 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 calculate, report and certify certain complex 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;

- 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 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 report information related to payments to health care providers, marketing expenditures or drug prices; state and local laws requiring the registration of pharmaceutical sales representatives; state laws regulating the manufacture and distribution of biopharmaceutical products; 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;

- U.S. laws and regulations prohibiting bribery and corruption, such as the U.S. 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; and

- 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 GDPR which imposes obligations and restrictions on the collection, use, and disclosure of personal data relating to individuals located in the EU and the EEA (including health data). See “—Our business operations may subject us to data protection laws, including the GDPR, the United Kingdom ("UK") GDPR, the CCPA and other similar laws."

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 UK GDPR, the CCPA and other similar laws.

The GDPR and UK GDPR apply to companies established in the EEA and UK, respectively, as well as to companies that are not established in the EEA or UK, respectively, 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 or

UK, respectively. If we conduct clinical trial programs in the EEA or UK (whether the trials are conducted directly by us or through a clinical vendor or collaborator), enter into research collaborations involving the monitoring of individuals in the EEA or UK, or market our products to individuals in the EEA or UK, we will be subject to the GDPR or UK GDPR, as applicable, which place stringent operational requirements for processors and controllers of personal data of individuals in the EEA and UK, respectively. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR or UK GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, temporary or definitive bans on data processing, or fines of up to 20 million Euros in the case of GDPR or £17.5 million in the case of UK GDPR or, in each case, 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.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the UK to the United States. On July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework (the "Privacy Shield") under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. This framework has been replaced by the E.U.-U.S. Data Privacy Framework, for which the EC adopted an adequacy decision in July 2023, and the UK Extension to the E.U.-U.S. Data Privacy Framework, which took effect in October 2023. While we do not currently rely upon these frameworks, we expect there to be legal challenges to this framework in the future, which could draw into question the legitimacy of other cross-border transfer mechanisms, including the standard contractual clauses on which we rely to transfer personal data from the EEA and UK to the U.S. and other jurisdictions. On June 4, 2021, the EC released two revised sets of standard contractual clauses for transfers of personal data from the EEA to the U.S. and has indicated that it will release additional revised standard contractual clauses in the future.

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. Other countries outside of the EEA and UK maintain different privacy laws that we are subject to which may further increase our costs of compliance and expose us to greater legal risk.

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 CCPA imposes many obligations for the collection, processing, and sharing of personal information of California residents. 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 the 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. Similar laws have been proposed or passed in more than half of the states in the U.S. and in the U.S. Congress. In addition, Washington state enacted the My Health, My Data Act, a health-focused consumer privacy law, which took effect in March 2024. This law imposes obligations related to the collection and sharing of certain health-related information that is not subject to HIPAA and that does not fall within certain other exceptions in the law. Other states have enacted, or are in the process of enacting, similar health-focused consumer privacy laws. Furthermore, all fifty U.S. states, the District of Columbia, Puerto Rico, and other U.S. territories have enacted data breach notification laws that require, among other things, notifications to state governments and/or the affected individuals in the event of a data breach. Such laws differ from one another, and may impose significant compliance burden. Further, we may at

times fail, or be perceived to have failed, to have complied with such laws. This could result in significant consequences, which include, but are not limited to, the imposition of fines and penalties, government enforcement actions, investigations and other proceedings, as well as additional reporting requirements and/or oversight.

Also of note, in June 2024, the Protecting Americans' Data from Foreign Adversaries Act of 2024 took effect. This law prohibits data brokers from making available certain personally identifiable sensitive data of U.S. individuals to "foreign adversary" countries, such as the PRC, and entities controlled by such countries. Additionally, in January 2025, the U.S. Department of Justice published a final rule implementing President Biden's Executive Order 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," which became effective in April 2025. This final rule prohibits certain data brokerage transactions and transactions involving certain bulk human 'omic data, including human genomic data and biospecimens from which such data can be derived, with restricted jurisdictions, such as the PRC, and "covered persons" that have certain ties to such restricted jurisdictions. The final rule also places restrictions on certain vendor, employment and investment agreements with such jurisdictions. These restrictions may affect our ability to engage in collaborations or license agreements with entities in restricted countries or with a nexus to such countries going forward. As such, we will need to review periodically our operations in comparison to developments in such laws. Achieving and sustaining compliance with applicable international, federal and state privacy, security, and breach reporting laws may prove time-consuming and costly. Failure to comply with any of these legal requirements could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations, including our clinical studies; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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 similar or identical technology and products, 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 intellectual property, particularly patents, in the United States and other countries, with respect to any proprietary technology and product candidates we develop. If we are unable to obtain or maintain patent protection of proprietary technology or product candidates by filing patent applications and/or in-licensing related intellectual property in commercially relevant jurisdictions, 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 identify, file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or

in a timely manner. 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 United States or in numerous foreign jurisdictions. Various courts, including the U.S. 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.

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. In addition, the scope of patent protection outside the United States is uncertain, and laws of foreign countries might not protect our rights to the same extent as the laws of the United States or vice versa.

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 patent applications issue as patents, they might not issue in a form that will provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents might be challenged in a variety of proceedings before courts or patent offices in the United States and abroad. Such challenges might result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology without payment to us, and/or limit the duration of the patent protection of our technology and product candidates. If the breadth or strength of 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.

For these reasons, our patent portfolio might not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to our technology and product candidates.

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

The USPTO and foreign patent offices have a number of procedural and documentary requirements that must be complied with during the patent application and prosecution process. Periodic fees must be paid to the USPTO and foreign patent offices at several stages or annually over the lifetime of issued patents and pending patent applications. In certain circumstances, we might rely on our licensing partners to meet procedural,

documentary, and fee requirements of the relevant patent agency. With respect to our patents, we rely 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, 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. If we or our licensors fail to maintain 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.

We may not be able to protect our intellectual property and proprietary rights throughout the world.
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 available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, third parties may attempt to develop and/or commercialize competitive products in foreign countries where we do not have any patent protection and/or where legal recourse may be limited. Further, we may not be able to prevent third parties from importing products made using our inventions into the United States or other jurisdictions. This may have a significant commercial impact on our business operations.

Proceedings to enforce our intellectual property 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 even if we do prevail, 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.

Changes to patent laws in the United States and other jurisdictions could diminish the value of our patents, 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 could increase the uncertainties and costs surrounding the prosecution of our patent applications and the maintenance, enforcement or defense of our issued patents, all of which could have a material adverse effect on our business. For example, in 2023, patent reform in the EU created a unitary patent and established a Unified Patent Court ("UPC"). The unitary patent facilitates validation of a patent granted by the European Patent Office in the EU member states that participate in the unitary patent. The UPC is a centralized body with jurisdiction over actions for preliminary injunctions, infringement, and revocation of patents granted by the European Patent Office. While the UPC has exclusive jurisdiction over unitary patents, patentees that do not utilize the unitary patent for validation can opt existing or future patents out of the jurisdiction of the UPC. There are both risks and benefits associated with pursuing Unitary Patents and with submitting to the jurisdiction of the UPC in the absence of a Unitary Patent. For example, because the UPC is a relatively new forum, little precedent exists, and the manner in which European patent law will be applied by the UPC is unpredictable, which presents potential risks to a patent’s scope and enforceability. In addition, an unfavorable outcome before the UPC could result in a European patent being invalidated in all participating member states. In comparison, European patents that are not under the jurisdiction of the UPC must be litigated separately in each member state, which causes patent challengers to incur additional costs and leaves open the possibility that a challenged patent could be affirmed in some member states, even if it is invalidated in others. From an enforcement perspective, the ability to assert patents against infringers under the UPC system could have significant financial benefits for a patentee, due to the ability to litigate in a single forum, rather than in each individual member state.

Currently, we do not have any unitary patents and we have opted out of UPC jurisdiction for our existing European patents. While we have and will continue to make case-by-case decisions about whether to pursue unitary patents or to elect the jurisdiction of the UPC, we cannot be certain that a more favorable outcome could be achieved if the opposite decision were made. We also cannot be certain whether the legal precedent of the UPC will evolve in a manner that is more or less favorable to us than the precedent of individual member states in a given situation or for a given patent.

In addition to legislative changes, 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. Further, political changes in government leadership both within and outside of the U.S. could result in changes to national patent laws and regulations or multi-country intellectual property treaties, which could impact patent enforcement in the U.S. and internationally. 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.

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. These factors might mean fewer suitable licensing opportunities for us, as well as higher acquisition or licensing costs.

If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our development and/or commercialization of the affected product candidates. Even if we are able to obtain a license, the terms may be unfavorable; for example, it may require substantial licensing or royalty payments, or be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain third-party intellectual property rights or to maintain our existing intellectual property rights, 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 upon us certain obligations, 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 and royalty payments, and insurance 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 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 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 may result in our loss of rights or our having to

negotiate new or reinstated agreements with less favorable terms, which would impede, delay or prohibit the further development or commercialization of any 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.

The resolution of any contract disagreement that may arise could narrow the scope of our rights to the relevant intellectual property or technology, could increase our financial or other obligations under the relevant agreement, or could result in loss of some or all rights under the license agreement. 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. Any of these outcomes 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.

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 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 a patent term extension for any product candidates we might develop, our business might be materially harmed.
In the United States, the term of a patent that covers an FDA-approved drug may be eligible for PTE of up to five years beyond the expiration date of the patent, 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, and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. 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 jurisdictions. While we expect to apply for PTE on patents covering our product candidates, there is no guarantee that such extensions will 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. Furthermore, for licensed patents, we might not be able to control whether a petition to obtain a PTE is filed or obtained from the USPTO and/or foreign patent office(s). If we are unable to obtain any PTE, or if the term of extension is less than we request, our business, financial condition, results of operations and prospects could be materially harmed.

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 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. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies. 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. Further, we cannot guarantee that we have entered into confidentiality agreements with each party that may have or has had access to our trade secrets or proprietary technology.

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, 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.
We might be unable to successfully register our trademarks and trade names, and/or to establish name recognition based on our trademarks and trade names, which could result in substantial costs and diversion of resources, and could adversely impact our ability to compete effectively. In addition, 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 them. At times, competitors may adopt trademarks or trade names similar to ours, impeding our ability to build brand identity, and possibly leading to market confusion. In addition, we could be subject to trademark or trade name infringement claims brought by owners of other registered trademarks or trade names

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 our patents or other intellectual property. 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.

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 our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not yielding an issued patent. A court may also refuse to enjoin a third-party from using the technology at issue, for example, on the basis that 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 or services. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our research programs and clinical trials.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO might 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 interference or derivation proceedings might fail and, even if successful, might result in substantial costs.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and other proceedings, there is a risk that some of our confidential information or trade secrets could be disclosed during litigation. This 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.

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 patents, trade secrets or other intellectual property. For example, we may have inventorship or ownership disputes that 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 ownership of our 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.

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

Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are pursuing development candidates. 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.

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. Adversarial proceedings might also 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 might provide little or no deterrence or protection. 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.

A court could hold that third-party patents are valid, enforceable and infringed by our product candidates or activities. To successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity, which is a high burden that requires clear and convincing evidence of invalidity. There is no assurance that a court would invalidate the claims of any such U.S. patent.

Parties making claims against us may obtain injunctive or other equitable relief that could block our ability to commercialize our product candidates. In the event of a successful claim of infringement against us, we may 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/or redesign our infringing products, which may not be possible or practical. In addition, 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 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. Further, a license could require us to make substantial licensing and royalty payments.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information or trade secrets of such third parties, 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 or engaged by universities or other pharmaceutical or biotechnology companies. 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 obtained, used, infringed, misappropriated, disclosed or otherwise violated the intellectual property rights of third parties. Any resulting 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.

Intellectual property litigation or other legal proceedings relating to intellectual property could cost substantial resources.
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. In addition, there could be public announcements involving such proceedings, 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 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 resources to conduct such litigation or proceedings adequately. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

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 intellectual property rights;
- it is possible that our pending or future patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable;
- 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, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us 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 Pharmaceuticals, Inc. (now part of AstraZeneca), 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.

If employees seek alternate employment, we may have to increase reliance on external support to advance our operations. Any workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

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 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. We are aware that a third party accessed the computer systems of one of our contractors and while we believe that such access did not result in loss of our proprietary data or disrupt our operations, we or our contractors may be subject to attacks in the future that could harm our business. 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 Our Common Stock

An active trading market for our common stock may not be sustained.
If a market for our common stock 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.

Our failure to meet the listing standards of the Nasdaq could result in the delisting of our common stock. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue to operate as a going concern would be substantially impaired.
On February 24, 2025, we received a deficiency notice (the "Notice"), from the Listing Qualifications Staff (the "Staff of Nasdaq"), notifying us that, for the prior 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, thereby failing to satisfy the minimum closing bid price requirement set forth in the continued listing requirements of Nasdaq Listing Rule 5450(a)(1), (the "Bid Price Requirement"). The Notice had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until August 25, 2025, (the "Compliance Date"), to regain compliance with the Bid Price Requirement by having shares of our common stock maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days before the Compliance Date.

As we had not regained compliance with the Bid Price Requirement by the Compliance Date, we filed an application to transfer the listing of our common stock from the Nasdaq Global Select Market to the Nasdaq Capital Market. On August 26, 2025, we received approval from the Staff of Nasdaq to transfer the listing of our common stock from the Nasdaq Global Select Market to the Nasdaq Capital Market, (the "Approval"). Our common stock was transferred to the Nasdaq Capital Market effective as of the opening of business on August 29, 2025 and has continued to trade under the symbol "RLYB." The Nasdaq Capital Market operates in substantially the same manner as the Nasdaq Global Select Market, and listed companies must meet certain financial requirements and comply with Nasdaq's corporate governance requirements. As a result of the Approval, we were granted an additional 180-day grace period, or until February 23, 2026, (the "Second Compliance Date"), to regain compliance with the Bid Price Requirement.

On January 26, 2026, our stockholders voted in favor of an amendment to our amended and restated certificate of incorporation to effect a reverse stock split of our issued and outstanding common stock at a ratio ranging from 1-for-5 shares up to 1-for-20 shares, which ratio would be selected by our board of directors. On January 26, 2026, our board of directors approved a 1-for-8 reverse stock split of our issued and outstanding common stock. On February 6, 2026, we effected a reverse stock split at a ratio of 1-for-8 shares. The primary goal of the

reverse stock split was to increase the per share market price of our common stock to meet the Bid Price Requirement.

On February 24, 2026, we were notified by the Staff of Nasdaq that the closing bid price of our common stock had been $1.00 per share or greater for at least 10 consecutive business days, from February 6, 2026 to February 23, 2026. Accordingly, we have regained compliance with the Bid Price Requirement.

Although we regained compliance with the Bid Price Requirement following the reverse stock split, there can be no assurance that we will continue to meet the Bid Price Requirement, or any other Nasdaq continued listing requirements, in the future. If we fail to meet any of these requirements, including the Bid Price Requirement, Nasdaq may again notify us that we have failed to meet the minimum listing requirements and initiate the delisting process. If our common stock were delisted from Nasdaq, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board, but there can be no assurance that our common stock will be eligible for trading on such alternative exchange or market. Additionally, if our common stock were delisted from Nasdaq, the liquidity of our common stock would be adversely affected, the market price of our common stock could decrease, our ability to obtain sufficient additional capital to fund our operations and to continue to operate as a going concern would be substantially impaired and transactions in our common stock could lose federal preemption of state securities laws. Furthermore, there could also be a further reduction in our coverage by securities analysts and the news media and broker-dealers may be deterred from making a market in or otherwise seeking or generating interest in our common stock, which could cause the price of our common stock to decline further. Moreover, delisting may also negatively affect our collaborators', vendors', suppliers' and employees' confidence in us and employee morale.

The market price of our common stock may be volatile, which could result in substantial losses for investors.
Shares of our common stock were offered in our IPO in July 2021 at a price of $104.00 per share and between the date of our IPO and March 6, 2026, the closing price per share of our common stock has ranged from as low as $2.00 to as high as $187.20. 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;
- 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;
- 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 Annual Report on Form 10-K.

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. 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.

If securities analysts stop publishing 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 is influenced in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline.

A significant portion of our total outstanding shares may be sold into the market, 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. As of March 6, 2026, we have 5,289,675 shares of common stock outstanding. All of these shares may be resold in the public market immediately, unless held by our affiliates who are subject to volume limitations under Rule 144. As of March 6, 2026, we also have pre-funded warrants to purchase up to an aggregate of 416,673 shares of common stock outstanding. We may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder’s election upon 61 days’ notice to us subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99%.

Moreover, as of December 31, 2025, certain holders of our common stock 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. On May 9, 2023, we registered an aggregate of 1,543,950 shares of common stock held by holders with registration rights, for resale, pursuant to a registration statement on Form S-3. In addition, we have entered into the Sales Agreement with TD Cowen to offer and sell shares of our common stock having an aggregate offering price of up to $100,000,000, from time to time, through an at-the-market offering program. We also registered an aggregate of 1,737,094 shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding

options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. 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 have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors and executive officers and their affiliates beneficially own shares representing approximately 25% of our outstanding common stock as of March 6, 2026. 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.

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 JOBS Act and we may remain an emerging growth company (an "EGC") 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 ("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. 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 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 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 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 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 (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 designates 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 provides that, subject to limited exceptions, the state or federal courts (as appropriate) within the State of Delaware are 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 does 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 does 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.

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, tariffs, 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 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, (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. 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. Additionally, the IRA was enacted in August 2022.

Among other things, the IRA implemented a one percent (1%) excise tax on certain repurchases (including redemptions) of stock by publicly traded domestic corporations, and a corporate alternative minimum tax of fifteen percent (15%) on book income of certain large corporations. Future changes in tax laws could have a material adverse effect on our business, cash flows, financial condition or results of operations. In particular, proposed tax legislation 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.

H.R. 1., also known as the One Big Beautiful Bill Act (the "OBBBA"), was enacted on July 4, 2025. The legislation includes several provisions that may impact the timing and magnitude of certain tax deductions. Key provisions include the permanent extension of several business tax benefits originally introduced under the TCJA.

Potential clinical trial or product liability lawsuits against us could cause us to incur substantial liabilities and, if we continue to progress the development of our product candidates, could limit commercialization of any products that we may develop.
If we continue to progress the development of our product candidates, 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 and geopolitical instability 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, including changes in tariffs and other trade restrictions. A severe or prolonged economic downturn, period of sustained increased inflation, tariffs and other trade restrictions 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. Further, geopolitical instability outside the United States may also impact our operations or affect global markets, such as the invasion of Ukraine by Russia and the Israel-Hamas war. While we do not currently conduct clinical trials in Ukraine, Russia, or the Middle East, we cannot be certain what the overall impact of these events will be on our business or on the business of any of our third-party partners, including our contract research organizations, contract manufacturers or other partners. The impact of these events could also expand into other markets where we do business. A weak or declining economy could 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 current geopolitical tensions, the economic climate and the financial market conditions could adversely impact our business.

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

As a public company, we have incurred, 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 Capital 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 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. 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 SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K with the SEC. 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, 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 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.

Item 1B. Unresolved Staff Comments
None.

Item 1C. Cybersecurity

Risk Management and Strategy
We have developed and implemented a cybersecurity risk management program that is designed to identify, assess and manage material risks from cybersecurity threats and to protect the security, confidentiality, integrity, and availability of our critical systems and information. Our information security program is developed using industry standards and best practices as a guide, including the National Institute of Standards and Technology (“NIST”) Cybersecurity Framework. The program includes penetration tests and periodic vulnerability scans, and evaluations by external service providers. The results of these evaluations are shared with senior management and the audit committee of the board of directors, where appropriate.

Our cybersecurity risk management program is integrated into our overall enterprise risk management processes and shares common methodologies, reporting channels and governance processes that apply across our enterprise risk management processes to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- Risk assessments designed to help identify material cybersecurity risks to our critical systems, information, product candidates and our broader enterprise information technology ("IT") environment.
- A team principally responsible for managing: (a) our cybersecurity risk assessment processes, (b) our security controls, and (c) our response to cybersecurity incidents.
- The use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls as part of our operational security model.
- Threat intelligence that informs our third party IT service provider and us about new vulnerabilities and risks that require timely intervention or remediation.
- Cybersecurity awareness training of our employees, incident response personnel, and senior management.
- A cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

As of the date of this Annual Report on Form 10-K, we have not experienced a cybersecurity incident that resulted in a material effect on our business strategy, results of operations, or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such risks or any future material incidents.

Governance
The audit committee of our board of directors has primary responsibility for oversight of our information security program. Our cyber security program is managed by our third party IT service provider together with internal personnel. Our service provider and internal personnel work together to assess the environment, potential threats and responses.

Item 2. Properties.
Our corporate headquarters is located at 234 Church Street, New Haven, CT 06510, where we lease and occupy 4,500 square feet of office space. The current term of our lease in New Haven expires September 30,

2027. We believe that this office space is sufficient to meet our current needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. 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.

Item 4. Mine Safety Disclosures.
Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information
Our common stock is currently listed on the Nasdaq Capital Market under the symbol "RLYB."

Stockholders
As of December 31, 2025, there were 12 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy
We have never declared or paid 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information provided in the following table is as of December 31, 2025:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights and outstanding nonvested restricted stock units (1)	Weighted-average exercise price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance under equity compensation plans (3)
Equity compensation plans approved by security holders	666,883	$ 43.42	684,971
Equity compensation plans not approved by security holders	—	—	—

(1) Reflects 628,280 shares of common stock to be issued upon exercise of outstanding options under our 2021 Equity Incentive Plan and 38,603 outstanding restricted stock units that were issued under the 2021 Equity Incentive Plan.
(2) The weighted-average exercise price is calculated based on the exercise prices of outstanding options and does not include outstanding restricted stock units (which have no exercise price).
(3) Includes 590,690 shares available for future issuance under the 2021 Equity Incentive Plan and 94,281 shares available for future issuance under the 2021 Employee Stock Purchase Plan. The number of shares of our common stock delivered in satisfaction of awards under the 2021 Equity Incentive Plan will not be reduced by (i) any shares withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements or (ii) any shares underlying any portion of an award that is settled in cash or that expires, becomes unexercisable, terminates or is forfeited to or repurchased by us without the delivery (or retention, in the case of restricted or unrestricted stock) of shares of our common stock. The number of shares available for delivery under the 2021 Equity Incentive Plan will not be increased by any shares that have been delivered under the 2021 Equity Incentive Plan and are subsequently repurchased using proceeds directly attributable to stock option exercises. In addition, the number of shares

reserved for issuance under the 2021 Equity Incentive Plan automatically increases on January 1st of each year from 2022 to 2031 by the lesser of (i) five percent of the number of shares of the Company's common stock outstanding as of such date and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. The number of shares reserved for issuance under the 2021 Employee Stock Purchase Plan automatically increases on January 1st of each year from 2022 to 2031 by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date (ii) 72,831 shares of the Company's common stock, and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date (up to a maximum of 764,725 in the aggregate).

Item 6. Reserved

Item 7. 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 our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, 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 "Cautionary Note Regarding Forward-Looking Statements."

Our Business

We are a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Our lead program, RLYB116, is a differentiated complement C5 inhibitor with the potential to treat diseases of complement dysregulation. In addition, RLYB332, a long-acting MTP-2 antibody for the treatment of diseases of iron overload is currently in preclinical development.

Recent Developments

On March 1, 2026, we entered into the Merger Agreement with Candid, a clinical-stage biotechnology company advancing a leading portfolio of TCE therapeutics for autoimmune diseases, and Merger Sub, a wholly owned subsidiary of Rallybio. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into Candid, with Candid surviving as a wholly owned subsidiary of Rallybio. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Concurrently with the execution and delivery of the Merger Agreement, certain investors entered into subscription agreements with Candid, pursuant to which such investors have agreed to purchase, immediately prior to the Merger, shares of Candid common stock representing an aggregate commitment of approximately $505.5 million in the Concurrent Financing. The shares of Candid common stock that are issued in the Concurrent Financing will be or will have the right to be, respectively, converted into shares of Rallybio Common Stock in the Merger.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, (a) each then-outstanding share of common stock or preferred stock of Candid (each such share, a "Candid Share") (excluding any share described in clauses (b) or (c) below and Candid Shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Rallybio Common Stock, calculated in accordance with the Exchange Ratio, (b) each Candid Share issued in the Concurrent Financing will be converted into the right to receive a number of shares of Rallybio Common Stock calculated in accordance with the Merger Agreement, (c) any Candid Shares held as treasury shares or held or owned by Rallybio, Merger Sub or any subsidiary of Rallybio or Candid immediately prior to the Effective Time will be canceled and shall cease to exist, and no consideration shall be delivered in exchange therefor. Each then-outstanding option to purchase Candid Shares will be converted into an option to purchase Rallybio Common Stock, subject to adjustment as set forth in the Merger Agreement.

Under the Exchange Ratio and Concurrent Financing Exchange Ratio formulas in the Merger Agreement, immediately after the Closing, on a pro forma basis and based upon the number of shares of Rallybio Common Stock expected to be issued in connection with the Merger, pre-Merger equityholders of Candid (other than investors in the Concurrent Financing) are expected to own approximately 57.55% of the combined company,

pre-Merger equityholders of Rallybio are expected to own approximately 3.65% of the combined company and the Investors in the Concurrent Financing are expected to own approximately 38.80% of the combined company (assuming proceeds from the Concurrent Financing of $505.5 million), in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) a valuation for Rallybio of $47.5 million (assuming Rallybio Net Cash of $37.5 million as of the Closing), (ii) a fixed valuation for Candid of $750.0 million, and (iii) the relative capitalization of Rallybio and Candid. The percentage of the combined company that each party's equity holders will own following the Closing is subject to certain adjustments as described in the Merger Agreement, including the amount of the final Rallybio Net Cash at Closing.

Immediately prior to the Effective Time, Rallybio and a rights agent are expected to enter into a CVR Agreement, pursuant to which holders of record of certain Rallybio securities as of the close of business on the last business day prior to the day on which the Effective Time occurs will receive one CVR for each outstanding share of Rallybio Common Stock, prefunded warrant, Rallybio restricted stock unit or In the Money Parent Option (as defined in the CVR Agreement) held as of such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to receive their pro rata share of (i) all of the net proceeds (including cash the value of stock to the extent listed on a national exchange, at the time of disposition), if any, received by Rallybio as a result of payments made to Rallybio of any upfront, milestone, royalty and other payments received under any disposition agreement related to Rallybio's Legacy Assets, and (ii) all of the cash proceeds, if any, received from Recursion under the Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion, Exscientia Ventures I, Inc., Rallybio Corporation and Rallybio IPB, LLC. For a period of one year after the Closing Date, Rallybio will use commercially reasonable efforts to effect the disposition of the Legacy Assets. Such net proceeds will be subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred or other liabilities borne by Rallybio or its affiliates in respect of the Legacy Assets, and losses incurred by Rallybio or its affiliates due to a third-party proceeding in connection with such disposition.

We completed a confirmatory PK and PD study of RLYB116 in healthy volunteers in 2025 and reported data in the first quarter of 2026.

In July 2025, we entered into a Membership Interest Purchase Agreement (the "ENPP1 Purchase Agreement") with Recursion Exscientia Ventures I, Inc., an indirect wholly-owned subsidiary of Recursion ("Buyer") and Rallybio IPB, LLC, a wholly-owned subsidiary of Rallybio Corporation to sell our interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Buyer (a subsidiary of our joint venture partner Recursion) (the "JV Sale"). In connection with the JV Sale, we received a total of $20.0 million in the third quarter of 2025 including $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. We are eligible to receive a $5.0 million milestone payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by REV-I. We may also be eligible to receive certain payments in the event of Recursion's sale of the REV102 program.

In April 2025, we announced the discontinuation of our RLYB212 program for the prevention of FNAIT based on PK data from the Phase 2 clinical trial that demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy.

Complement Dysregulation

RLYB116 is an innovative, once-weekly, small volume, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-related diseases. We have completed two Phase 1 clinical trials in healthy participants that included the study of RLYB116 as both a SAD and a MAD. After the first Phase 1 clinical trial, we completed manufacturing process enhancements that were designed to improve the tolerability of RLYB116. In 2025, we completed the confirmatory Phase 1 clinical trial evaluating the PK/PD properties of RLYB116. The confirmatory trial achieved its two key objectives including: a significant improvement in the tolerability of RLYB116 and demonstration of complete and sustained inhibition of terminal complement. These results support the study of RLYB116 as a potential best-in-class therapeutic for multiple complement mediated diseases.

Hematological Disorders

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load

and treats ineffective erythropoiesis. In 2024, we re-engineered RLYB331 to extend its half-life and completed non-clinical studies that demonstrated favorable tolerability, dose-dependent PK, and sustained PD effects with RLYB332, a long-acting version of RLYB331. These findings, which were presented in a poster at the 66th annual meeting of ASH, support the continued development of RLYB332 as a potentially best-in-class therapeutic for treating diseases of iron overload.

In December 2022, we entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration combined AbCellera Biologics Inc.'s ("AbCellera's") antibody discovery engine with our clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients.

Our Operations

Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the 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 and conducting 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 programs. 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. From our inception and prior to our initial public offering ("IPO"), we received proceeds of approximately $182.5 million from equity financings. In August 2021, we closed our IPO and issued and sold 891,250 shares of common stock, inclusive of 116,250 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $104.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In November 2022, we completed a follow-on offering of approximately $54.8 million pursuant to which we issued 725,456 shares of common stock, inclusive of 100,456 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at a price of $48.00 per share and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 416,673 shares of common stock at a price of $47.9992, which represents the per share public offering price for the shares less the $0.0008 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

In April 2024, we entered into a securities purchase agreement (the "JJDC Securities Purchase Agreement") with Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"), pursuant to which we sold to JJDC, in an unregistered offering, 454,545 shares of our common stock at a price of $14.56 per share, which represented a 10% premium on our closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses. We agreed, among other things, to file with the SEC a registration statement covering the resale of the shares, which we filed on May 10, 2024.

In July 2025, we announced that we had entered into the ENPP1 Purchase Agreement to sell our interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Buyer (a subsidiary of our joint venture partner Recursion). In connection with the JV Sale, we received a total of $20.0 million in the third quarter of 2025 including $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. We are eligible to receive a $5.0 million milestone cash payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by REV-I. We may also be eligible to receive certain payments in the event of Recursion's sale of the REV102 program.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $54.7 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2028, although we anticipate that the proposed merger with Candid will be completed in 2026. See "—Liquidity and Capital Resources."

We have incurred significant operating losses since inception, including net losses of $9.0 million and $57.8 million for the years ended December 31, 2025 and 2024, respectively. Our loss for the year ended December 31, 2025 included a $23.0 million gain in connection with the JV Sale in 2025. As of December 31, 2025, we had an accumulated deficit of $302.0 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 have not commercialized any products and have never generated revenue from the commercialization of any product. If we are unable to complete the proposed transaction with Candid, we may need to raise additional capital. There can be no assurances, however, that additional funding will be available on terms acceptable to us, or at all.

Components of Results of Operations

Revenue

We do not have any product candidates approved for sale and have not generated any revenue from product sales. In April 2024, we entered into a two-year collaboration agreement (the "J&J Collaboration Agreement") with Johnson & Johnson, through its wholly-owned subsidiary, Momenta Pharmaceuticals, Inc. ("J&J"). Our collaboration and license revenue to date is related to data collection and data submission performance obligations pursuant to the two-year J&J Collaboration Agreement to facilitate the advancement of research into products to address unmet needs relating to FNAIT. Pursuant to the J&J Collaboration Agreement, we received an upfront payment of $0.5 million from J&J for the information dissemination and data provision services under the agreement. We were also eligible to receive additional payments upon certain triggers related to the companies' FNAIT studies, however, in connection with our decision in April 2025 to discontinue development of RLYB212, we do not expect payments regarding the achievement of certain enrollment-related events.

We determined there were performance obligations as follows:

(1) Data collection and submission revenue – derived from Rallybio's ongoing management of the studies including the maintenance of a minimum site footprint, the license to utilize, and timely, semi-annual submission of the anonymized data, in the required formats.

(2) Dissemination of J&J materials & participant revenue – derived from Rallybio's dissemination of content, information or materials related to the J&J-Sponsored Studies that are developed by J&J and are provided by Rallybio for the purpose of disseminating such content, information, or materials to staff at Rallybio study sites to provide to potential eligible participants regarding J&J's independent study.

In April 2024, we also entered into the JJDC Securities Purchase Agreement. Under the terms of the JJDC Securities Purchase Agreement, JJDC made an equity investment purchasing 454,545 shares of common stock with a par value of $0.0001 per share for a share purchase price of $14.56 per share which includes a 10% premium for an aggregate purchase price of $6.6 million. The JJDC Securities Purchase Agreement contains provisions related to the registration of the shares and the restriction on the sale or transfer of the shares for a period of time. We determined the J&J Collaboration Agreement and JJDC Securities Purchase Agreement represented combined agreements. In accordance with Accounting Standards Codification 606, *Revenue Recognition* and Accounting Standards Codification Topic 820, *Fair Value Measurement*, total consideration of $1.2 million for the shares of common stock from the JJDC Securities Purchase Agreement, which represents the premium of $0.7 million and discount for lack of marketability of $0.5 million, has been allocated to revenue and will be recognized over the two year expected performance period.

Operating Expenses

Research and Development Expenses

Research and development expenses consist 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 ("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 expenses related to the manufacturing scale-up and fees paid to contract manufacturing organizations ("CMOs");

- employee-related expenses, including salaries, bonuses, benefits, share-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;
- expenses to acquire technologies, such as intellectual property, to be used in research and development including in-process research and development ("IPR&D") that has no alternative future use at the time of asset acquisitions;
- costs related to compliance with quality and regulatory requirements; and
- facilities, depreciation and other indirect costs allocated to employees and activities supporting our research and development efforts.

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 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, facility costs, 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 any product candidate is highly uncertain. If we are unable to complete the proposed transaction with Candid and continue to progress our product candidates, we will need to raise substantial additional capital in the future to fund the future development of our current programs. We intend to focus our near term research and development efforts on completing the ongoing activities and preparing our programs for a potential transaction or sale.

General and Administrative Expenses
General and administrative expenses consist primarily of salaries, benefits and share-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 expect our general and administrative expenses to increase in the short term in connection with activities to support the completion of the potential transaction with Candid.

Total Other Income, Net
Total other income, net, includes interest income earned on cash, cash equivalents and marketable securities, and income and expense items, including income related to the proceeds from the JV Sale.

Loss on Investment in Joint Venture
We recognize the pro-rata share of losses in the joint venture with Recursion (as successor in interest to Exscientia) on the consolidated statements of operations and comprehensive loss within the loss on investment in joint venture line item, with a corresponding change to the joint venture investment asset on the consolidated balance sheets for equity method investments for which we do not have a controlling interest in. In July 2025, we sold our interest in REV102 to Recursion.

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations:

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2025	2024	CHANGE
Revenue:			
Collaboration and license revenue	$ 858	$ 636	$ 222
Total revenue	858	636	222
Operating expenses:			
Research and development	19,597	41,507	(21,910)
General and administrative	14,325	19,625	(5,300)
Total operating expenses	33,922	61,132	(27,210)
Loss from operations	(33,064)	(60,496)	27,432
Total other income, net	24,960	4,960	20,000
Loss before equity in losses of joint venture	(8,104)	(55,536)	47,432
Loss on investment in joint venture	874	2,239	(1,365)
Net loss	$ (8,978)	$ (57,775)	$ 48,797

Revenue

Collaboration and license revenue was $0.9 million for the year ended December 31, 2025, compared to $0.6 million for the year ended December 31, 2024. The increase of $0.2 million in 2025 as compared to 2024 was due to our entrance into the J&J Collaboration Agreement in the second quarter of 2024 and the recognition of revenue related to the collaboration performance obligations.

Operating Expenses

Research and Development Expenses

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

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2025	2024	CHANGE
Direct research and development by program			
RLYB212	$ 6,291	$ 21,287	$ (14,996)
RLYB116	3,786	4,841	(1,055)
Other program candidates	(29)	1,901	(1,930)
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	8,798	12,488	(3,690)
Other expenses	751	990	(239)
Total research and development expenses	$ 19,597	$ 41,507	$ (21,910)

Research and development expenses were $19.6 million for the year ended December 31, 2025, compared to $41.5 million for the year ended December 31, 2024. The decrease of $21.9 million was primarily due to:

- a $15.0 million decrease in costs related to the development of RLYB212, primarily related to a decrease in clinical development costs, manufacturing costs and other related development costs as a result of our discontinuation of the FNAIT program in April 2025;
- a $1.1 million decrease in costs related to the development of RLYB116, primarily related to a decrease in manufacturing costs; which were partially offset by an increase in clinical development costs and other related development costs;

- a $1.9 million decrease in costs related to the development of other program candidates, primarily related to RLYB332 manufacturing costs and other related development costs; and
- a $3.7 million decrease in payroll and personnel-related expenses, primarily due to lower ongoing headcount during the year ended December 31, 2025 as compared to the same period in 2024; offset by an increase in personnel-related expenses due to the severance expense recognized in the second quarter of 2025 in connection with the workforce reduction, effective May 2, 2025.

General and Administrative Expenses
General and administrative expenses were $14.3 million for the year ended December 31, 2025, compared to $19.6 million for the year ended December 31, 2024. The decrease of $5.3 million was primarily due to:

- a $4.7 million decrease in personnel-related expenses, primarily related to lower ongoing headcount during the year ended December 31, 2025 as compared to the same period in 2024; offset by an increase in personnel-related expenses due to severance expense recognized in the second quarter of 2025 in connection with the workforce reduction, effective May 2, 2025; and
- a $0.6 million decrease primarily related to professional fees and other related general and administrative expenses; offset by an increase in legal fees.

Total Other Income, Net
Total other income, net, for the year ended December 31, 2025 was $25.0 million compared to $5.0 million for the year ended December 31, 2024. The increase in total other income of $20.0 million was primarily related to an increase in other income related to the JV Sale; offset by a decrease in interest income from marketable securities due to a lower excess cash balance.

Loss on Investment in Joint Venture
Loss on investment in joint venture for the year ended December 31, 2025 was $0.9 million compared to $2.2 million for the year ended December 31, 2024. The change was primarily due to the sale of our interest in REV102 in July 2025.

Liquidity and Capital Resources

Sources of Liquidity

On February 6, 2026, we executed a reverse stock split of our issued and outstanding common stock, par value $0.0001, at a ratio of 1-for-8 with a record date of December 30, 2025 (the “Reverse Stock Split”). All common stock, per share and related information included below have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split.

Since our inception, we have funded our operations primarily through equity financings. From our inception and prior to our IPO, we received proceeds of approximately $182.5 million from equity financings. In August 2021, we closed our IPO and issued and sold 891,250 shares of common stock, inclusive of 116,250 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $104.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In August 2022, we filed a Registration Statement on Form S-3 (the “Shelf”) with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $300.0 million. The Shelf was declared effective on August 15, 2022. Pursuant to General Instruction I.B.6 to Form S-3 (“Instruction I.B.6”), a company with a public float of less than $75.0 million measured at certain time periods may not issue securities under Registration Statements on Form S-3 in excess of one-third of its public float in a 12-month period. We are subject to the limitations of Instruction I.B.6, which may limit the amount of funds we can raise using the Shelf or any other Registration Statement on Form S-3. In connection with the Shelf, we also simultaneously entered into a Sales Agreement with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) ("TD Cowen"), which was amended on March 13, 2025 (as amended, the "Sales Agreement"). In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to

$9.55 million from time to time at prices through TD Cowen acting as our agent. Pursuant to the Sales Agreement, sales of our common stock, if any, will be made in sales deemed to be “at the market offerings” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"). Under the Sales Agreement, TD Cowen will be entitled to compensation equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of December 31, 2025, we had not sold any shares of common stock pursuant to the Sales Agreement.

In November 2022, we completed a follow-on offering of approximately $54.8 million consisting of 725,456 shares of common stock, inclusive of 100,456 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at the price of $48.00 per share, and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 416,673 shares of common stock at a price of $47.9992, which represents the per share public offering price for the shares less the $0.0008 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

In April 2024, we entered into the JJDC Securities Purchase Agreement, pursuant to which we sold to JJDC in an unregistered offering, 454,545 shares of our common stock at a price of $14.56 per share, which represented a 10% premium on our closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses. We agreed, among other things, to file with the SEC a registration statement covering the resale of the shares within 120 days following the closing of the offering. We filed this registration statement on May 10, 2024.

In July 2025, we announced that we had entered into the ENPP1 Purchase Agreement to sell our interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Buyer (a subsidiary of our joint venture partner, Recursion). In the third quarter of 2025, we received a total of $20.0 million in connection with the JV Sale, including $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. We are eligible to receive a $5.0 million milestone cash payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by REV-I. We may also be eligible to receive certain payments in the event of Recursion’s sale of the REV102 program.

As of December 31, 2025, we had $54.7 million of cash, cash equivalents and marketable securities.

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. See "Contractual Obligations" below.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months of the filing of this Annual Report on Form 10-K, and we anticipate that the proposed merger with Candid will be completed in 2026.

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 will depend primarily on our ability to complete the proposed transaction with Candid.

If we do not complete the proposed transaction with Candid and 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. Any future sales of equity will result in dilution to our existing stockholders. 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:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands)	2025	2024
Net cash used in operating activities	$ (29,813)	$ (49,282)
Net cash provided by investing activities	47,268	33,492
Net cash provided by financing activities	16	5,199
Net increase (decrease) in cash and cash equivalents	$ 17,471	$ (10,591)

Operating Activities

During the year ended December 31, 2025, net cash used in operating activities was $29.8 million as compared to $49.3 million for the year ended December 31, 2024. The decrease in net cash used in operating activities was primarily related to a decrease in research and development and general and administrative activities and changes in working capital.

Investing Activities

Net cash provided by investing activities was $47.3 million for the year ended December 31, 2025 as compared to $33.5 million for the year ended December 31, 2024. The increase of $13.8 million in net cash provided by investing activities was primarily related to proceeds of $46.5 million from maturities of highly-rated debt securities, in addition to an increase of $18.5 million primarily related to the proceeds of $20.0 million from the JV Sale, partially offset by purchases of highly-rated debt securities of $17.7 million during the year ended December 31, 2025, as compared to proceeds from maturities of highly-rated debt securities of $84.4 million, partially offset by purchases of highly-rated debt securities of $48.9 million during the year ended December 31, 2024.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $16 thousand, representing proceeds from the issuance of common stock under the stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2024 was $5.2 million, primarily representing proceeds from the issuance of common stock pursuant to the JJDC Securities Purchase Agreement, after deducting offering costs and accounting for the total consideration allocation related to the J&J Collaboration Agreement of $1.2 million.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2025:

	PAYMENTS DUE BY PERIOD				
(in thousands)	TOTAL	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating lease obligations	$ 190	$ 106	$ 84	$ —	$ —

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 Agreements” and “Business—Asset Purchase Agreements” included elsewhere in this Annual Report on Form 10-K for a description of these agreements.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. 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 Basis of Presentation and Principles of Consolidation” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, 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.

Share-Based Compensation

We account for share-based compensation in accordance with the Accounting Standards Codification 718, *Compensation—Stock Compensation*. Generally, share-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. Share-based compensation for awards with performance conditions are recognized over the service period when achievement of the performance condition is probable. We have elected to recognize the actual forfeitures by reducing the share-based compensation in the same period as the forfeitures occur. We classify share-based compensation in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipients’ payroll costs are classified.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield. See Note 2 “Summary of Significant Accounting Policies Basis of Presentation and Principles of Consolidation” of our consolidated financial statements for additional information on the assumptions utilized in the Black-Scholes option-pricing model.

Emerging Growth Company and Smaller Reporting Company
As an EGC under the 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 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 are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates 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 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, 2025 and 2024, 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, results of operations and footnote disclosures is disclosed in Note 2 “Summary of Significant Accounting Policies Basis of Presentation and Principles of Consolidation” to our consolidated financial statements for the year ended December 31, 2025 appearing elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.
We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.
The financial information required by Item 8 is located beginning on page F-1 of this Annual Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.
Our management, with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting.
Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, under the supervision and with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on the results of its evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Internal control over financial reporting includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting.
There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Director and Officer Trading Arrangements
During the fourth quarter of 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act, as amended) entered into, modified (as to amount, price or timing of trades) or terminated (i) contracts, instructions or written plans for the purchase or sale of our securities that are intended to satisfy the conditions specified in Rule 10b5-1(c) under the Exchange Act for an affirmative defense against liability for trading in securities on the basis of material nonpublic information or (ii) non-Rule 10b5-1 trading arrangements (as defined in Item 408(c) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.
Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

BOARD COMPOSITION AND STRUCTURE

Our certificate of incorporation states that the Board of Directors shall consist of not fewer than three and not more than fifteen members, and the precise number of directors shall be fixed by a resolution of the Board of Directors. Each director shall hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. Our certificate of incorporation provides that our directors may be removed only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of the outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. Any vacancy in the Board of Directors, including a vacancy that results from an increase in the number of directors, may be filled by a vote of the majority of the directors then in office.

Our certificate of incorporation provides that the Board of Directors is divided into three classes of directors. Each of our directors identified below serves in the class indicated. Subject to any earlier death, resignation or removal in accordance with the terms of our restated certificate of incorporation and bylaws, our Class II directors are currently serving until the 2026 annual meeting and will be those who are re-elected at the 2026 Annual Meeting of stockholders will serve until the 2029 annual meeting of stockholders; our Class III directors will serve until the 2027 annual meeting of stockholders; and our Class I directors will serve until the 2028 annual meeting of stockholders. Any additional directorships resulting from an increase in the number of directors will be apportioned by the Board of Directors among the three classes.

It is the Board of Directors' policy that directors should possess the highest personal and professional ethics, integrity and values, and be committed to representing the long-term interests of the Company's stockholders. The Board of Directors believes that the directors should possess a combination of skills, professional experience and diversity of viewpoints necessary to oversee the Company's business. Accordingly, the Board of Directors considers the qualifications of directors and director candidates individually and in the broader context of its overall composition and the Company's current and future needs.

The Board of Directors is currently comprised of ten members. Below is a list of the names, ages as of March 6, 2026, and classification of the individuals who currently serve as our directors.

Name	Age	Director Since	Position and Class
Martin W. Mackay, Ph.D.	69	2018	Chairman (Class I - term will expire 2028)
Paula Soteropoulos	58	2020	Director (Class I - term will expire 2028)
Stephen Uden, M.D.	68	2023	Director (Class II - term will expire 2026)
Helen M. Boudreau, M.B.A.	60	2020	Director (Class II - term will expire 2026)
Lucian Iancovici, M.D.	43	2020	Director (Class II - term will expire 2026)
Christine A. Nash, M.B.A.	53	2022	Director (Class II - term will expire 2026)
Wendy K. Chung M.D., Ph.D.	57	2022	Director (Class III - term will expire 2027)
Robert Hopfner, R.Ph., Ph.D., M.B.A.	53	2020	Director (Class III - term will expire 2027)
Ronald Hunt, M.B.A.	61	2018	Director (Class III - term will expire 2027)
Hui Liu, Ph.D., M.B.A.	53	2022	Director (Class III - term will expire 2027)

DIRECTOR BIOGRAPHIES

Information concerning our directors is set forth below. The biographical description of each director includes the specific experience, qualifications, attributes and skills that led to the Board of Directors' conclusion at the time of filing of this Annual Report on Form 10-K statement that each person listed below should serve as a director.

Class I Directors (Term Expires at 2028 Annual Meeting)

Martin W. Mackay, Ph.D., is a co-founder of Rallybio and Chairman of the Board of Directors. From January 2018 until August 2023, Dr. Mackay served as Chief Executive Officer and Chairman of the Board of Directors of Rallybio, and from August 2023 until December 2024 he served as Executive Chairman. From March 2013 to December 2017, Dr. Mackay served as the Executive Vice President and Global Head of Research &

Development at Alexion Pharmaceuticals, Inc., 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., 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 Charles River Laboratories International, Inc. and Sail Biomedicines. He previously served as a director of 5AM Acquisition Co. from October 2020 until April 2022. Dr. Mackay served on board of Novo Nordisk from 2018 through 2025, and on the board of SpringWorks Therapeutics through its acquisition by Merck KGaA in 2025. Dr. Mackay received a BSc First Class in microbiology from Heriot-Watt University and a Ph.D. in molecular genetics from the University of Edinburgh. We believe Dr. Mackay is qualified to serve on our Board of Directors because of his extensive experience serving on other boards and leading research and development organizations at both global pharmaceutical and biotechnology companies, which provides our Board of Directors with a valuable combination of expertise.

Paula Soteropoulos has served as a member of our Board of Directors since October 2020. Ms. Soteropoulos currently serves as Chairman of Ensoma, a private venture-backed company, and serves on the board of Directors of Metri Bio and Dianthus Therapeutics, Inc. She previously served as Chief Executive Officer and President of Akcea Therapeutics, Inc. a biopharmaceutical company, 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 Vice President and General Manager, Cardiovascular, Rare Diseases. Ms. Soteropoulos served for 11 years on the board of directors of uniQure N.V. Ms. Soteropoulos also serves on advisory boards of Chiesi USA and Kyowa Kirin North America. 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 board of directors of other public and private biopharmaceutical companies.

CURRENT DIRECTORS NOT STANDING FOR ELECTION AT THE ANNUAL MEETING

Class II Directors (Term Expires at 2026 Annual Meeting)
Stephen Uden, M.D., is a co-founder of, and has been Chief Executive Officer and President, and a director of, Rallybio since August 2023. From January 2018 until August 2023, Dr. Uden served as President, Chief Operating Officer and Chief Scientific Officer of Rallybio. 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 received a BSc in biochemistry and an M.B., B.S. in medicine from the University of London. We believe Dr. Uden is qualified to serve on our Board of Directors because of his executive management experience and research and scientific expertise at global pharmaceutical and biotechnology companies.

Helen M. Boudreau, M.B.A., has served as a member of our Board of Directors since September 2020. Since 2020, she has been Managing Director of Estuary Ventures LLC, providing board and advisory services. 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. ("Pfizer") 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. Earlier in her career, Ms. Boudreau worked at PepsiCo Inc. and YUM! Brands, Inc., McKinsey & Company and Bank of America Corporation. Ms. Boudreau currently serves as a board member of Shattuck Labs Inc. Ms. Boudreau previously served on the board of directors of Premier, Inc., Cara Therapeutics, Inc., Evaxion Biotech A/S, Proteostasis Therapeutics, Inc. and Reunion Neuroscience 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. Ms. Boudreau is Directorship Certified® by the National Association of Corporate Directors ("NACD") and earned the CERT Certificate in Cybersecurity Oversight from Carnegie Mellon University Software Engineering Institute and NACD. 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.

Lucian Iancovici, M.D., has served as a member of our Board of Directors since May 2020. Dr. Iancovici is currently a Partner of TPG, a global alternative asset manager, 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. Dr. Iancovici currently serves on the board of directors of Sionna Therapeutics, Inc. and on the boards of directors of several private companies. He is a board-certified internal medicine doctor, who trained at Columbia University Medical Center in New York prior to joining McKinsey & Company. Dr. Iancovici received his B.A. 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.

Christine A. Nash, M.B.A., has served as a member of our Board of Directors since April 2022. Since April 2018, Ms. Nash has been a principal at Chatiemac Consulting, LLC, a firm that provides strategic and commercial planning guidance to biotechnology companies and investors focused on the development of medications for rare diseases. From September 2021 until September 2022, Ms. Nash served as Board Chair and senior advisor to the President and Chief Executive Officer of The CM Group, an integrated healthcare agency focused on providing scientific and commercialization strategies and services to life sciences companies, where she also served as a member of the Board of Directors from August 2019 until September 2022. From 2007 to 2015, Ms. Nash held positions of increasing responsibility at Hyperion Therapeutics, Inc., including as Senior Vice President and Chief Commercial Officer since May 2012. Prior to Hyperion, from 2004 to 2007, Ms. Nash held various positions of increasing responsibility within the commercial organization at CoTherix, Inc. Ms. Nash's previous experience includes business development and product planning and management roles with Genesoft Pharmaceuticals Inc., Oncology Therapeutics Network, Eli Lilly and Company, and Imana, Inc. Ms. Nash holds an M.B.A and a B.A. with Honors in Public Policy, both from Stanford University. We believe that Ms. Nash is qualified to serve on our Board of Directors because of her extensive operational and business experience in the pharmaceutical and biotechnology industries, including executive leadership, and her experience overseeing commercial organizations and product launches.

Class III Directors (Term Expires at 2027 Annual Meeting)

Wendy K. Chung, M.D., Ph.D., has served as a member of our Board of Directors since August 2022. Dr. Chung is an American Board of Medical Genetics certified clinical and molecular geneticist. Since July 2023, Dr. Chung has served as the Chair of the Department of Pediatrics at Boston Children's Hospital and on the faculty of Harvard Medical School. From February 2014 until July 2023, she led the Precision Medicine Resource in the Irving Institute at Columbia University. From July 2017 until July 2023, Dr. Chung was the Kennedy Family Professor of Pediatrics and Medicine at Columbia University, and had been on the faculty of Columbia University since 2002. Dr. Chung received her B.A. in Biochemistry from Cornell University, her M.D. from Cornell University Medical College, and her Ph.D. in Genetics from The Rockefeller University. We believe that Dr. Chung is qualified to serve on our Board of Directors because of her extensive experience in medicine and research, and her service on other boards.

Robert Hopfner, R.Ph., Ph.D., M.B.A., 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 Evommune, Inc., and on the boards of directors of a number of private life sciences companies. Dr. Hopfner previously served on the board of directors of Vaxcyte, Inc., Oculis Holding AG, and Inozyme Pharma Inc.. Dr. Hopfner received 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 Hunt, M.B.A., has served as a member of our Board of Directors since 2018. 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 director of Iterum Therapeutics, Ltd., a clinical-stage company, and on the boards of a number of private pharmaceutical and healthcare companies. Mr. Hunt previously served on the board of directors of Harpoon Therapeutics, Inc. Mr. Hunt received 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 board of directors of other public and private biopharmaceutical and biotechnology companies.

Hui Liu, Ph.D., M.B.A., has served as a member of our Board of Directors since April 2022. Dr. Liu has been the Chief Executive Officer and board member of Olethros B.V. since August 2025. Dr. Liu has also been Chief Operating and Business officer of Gyes B.V. since August 2025. Until July 2024, Dr. Liu was Chief Business Officer since December 2015 and Head of Merus U.S. since October 2018 of Merus N.V., a clinical-stage oncology company. From 2013 to 2015, Dr. Liu served as Vice President and Global Head, Business Development & Licensing, Oncology, and from 2009 to 2012 as Vice President and Global Head, Business Development & Licensing, Vaccines & Diagnostics, at Novartis AG. Prior to Novartis, Dr. Liu held positions of increasing responsibility in business development at Pfizer, Inc. from 2004 to 2009 and in the R&D organization at Pfizer and its predecessor company Warner-Lambert from 1997 to 2001. From 2001 to 2004, Dr. Liu was an investment banker at Goldman Sachs and Citigroup. Dr. Liu received a Ph.D. in molecular biology and an M.B.A. in finance from the University of Michigan and a B.S. in biology from Peking University. We believe that Dr. Liu is qualified to serve on our Board of Directors because of his extensive operational and business experience in the pharmaceutical and biotechnology industries, including executive leadership, and his transactional experience.

Board Meetings and Attendance

The Board of Directors held 22 meetings during the year ended December 31, 2025. Each of the directors attended at least seventy-five percent (75%) of the meetings of the Board of Directors and the committees of the Board of Directors on which he or she served during the year ended December 31, 2025 (in each case, which were held during the period for which he or she was a director and/or a member of the applicable committee and excluding any meetings in which a director was an interested party).

While we do not have a formal policy regarding director attendance at the annual meeting of stockholders, we expect our Board members to prepare for, attend and participate in all Board and applicable committee meetings, including by means of remote communication. All members of our Board of Directors attended the 2025 Annual Meeting.

Board of Directors Leadership Structure

Dr. Mackay serves as Chairman of the Board of Directors. From August 1, 2023 until December 31, 2024, Dr. Mackay served as Executive Chairman, and prior to August 1, 2023 served as Chief Executive Officer and Chairman.

In December 2023, the independent directors designated a Lead Director, which is a role that is similar to the role of an independent Chairman. Ms. Soteropoulos has served as Lead Director since December 2023. As set forth in Rallybio's Corporate Governance Guidelines, the Lead Director presides at meetings of the Board at which the Chairman, who is not currently independent, is not present, including executive sessions of our independent directors, serves as an independent point of contact for stockholders, and has other duties described in Rallybio's Corporate Governance Guidelines, which are available on our website.

The independent members of our Board of Directors have periodically reviewed our Board of Directors' leadership structure and have determined that the Company and our stockholders are well served with this structure. Dr. Mackay's former service as chief executive officer provides him with valuable insights into the Company's programs, operations, strategy and culture. In addition, Dr. Mackay serves on the board of directors of three public companies, and his corporate governance experience is incorporated into his leadership of our Board of Directors. Our Board of Directors believes that it is in the best interests of the Company for our Board of Directors to make a determination regarding whether or not to separate the roles of any chairperson and the Chief Executive Officer based on the then-current circumstances. Dr. Mackay has not served as Chief Executive Officer since August 2023.

The Board of Directors' Role in Risk Oversight

The Board of Directors plays an important role in risk oversight at Rallybio. Management is responsible for day-to-day management of risks, while the Board of Directors, through direct decision-making authority with respect

to significant matters, as well as through the oversight of management by the Board of Directors and its committees, is responsible for oversight of risk management. In particular, the Board of Directors administers its risk oversight function through (1) the review and discussion of regular periodic reports by the Board of Directors and its committees on topics relating to the risks that Rallybio faces, (2) the required approval by the Board of Directors (or a committee of the Board of Directors) of significant transactions and other decisions, (3) the direct oversight of specific areas of Rallybio's business by the Audit, Compensation and Nominating and Corporate Governance Committees, and (4) regular periodic reports from the auditors and other outside consultants regarding various areas of potential risk, including, among others, those relating to our internal control over financial reporting. The Board of Directors relies on management to bring significant matters impacting Rallybio to the attention of the Board of Directors.

The committees of the Board of Directors play an important role in overseeing the management of the Company's risks, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The appropriate Board committee or the Board of Directors discusses with management our significant risks, and the steps we take to manage risks. If a committee of the Board of Directors is responsible for evaluating and overseeing a particular risk, such as cybersecurity risks, which is overseen by the Audit Committee, the chair of the committee reports on the discussion to the Board of Directors, which enhances coordination of risk oversight among the committees and the Board of Directors.

Pursuant to the Audit Committee's charter, the Audit Committee is responsible for reviewing and discussing with management and Rallybio's independent registered public accounting firm, Rallybio's system of its critical accounting practices, and policies relating to risk assessment and management. As part of this process, the Audit Committee discusses Rallybio's major financial risk exposures and steps that management has taken to monitor and control such exposure. In addition, the Audit Committee has established procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submissions by employees of concerns regarding accounting, internal accounting controls, auditing and compliance matters.

Because of the role of the Board of Directors and the Audit Committee in risk oversight, the Board of Directors believes that any leadership structure that it adopts must allow it to effectively oversee the management of the risks relating to Rallybio's operations. The Board of Directors acknowledges that there are different leadership structures that could allow it to effectively oversee the management of the risks relating to the Company's operations and believes its current leadership structure enables it to effectively provide oversight with respect to such risks.

BOARD COMMITTEES

The Board of Directors has a standing Audit, Compensation and Nominating and Corporate Governance Committee. Each of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is comprised solely of independent directors, and is described more fully below. Each committee operates pursuant to a written charter and each reviews and assesses the adequacy of its charter periodically. The charters for each committee are all available on our website (www.rallybio.com) under the "Investors" section.

The following table describes which directors currently serve on each of the Board of Directors' committees.

Name	Nominating and Corporate Governance Committee		Compensation Committee		Audit Committee	
Stephen Uden, M.D.						
Martin W. Mackay, Ph.D.						
Helen M. Boudreau, M.B.A.					•	(1)
Wendy K. Chung, M.D., Ph.D.	•					
Robert Hopfner, R.Ph., Ph.D., M.B.A.	•				•	
Ronald Hunt, M.B.A.	•				•	
Lucian Iancovici, M.D.			•			
Hui Liu, Ph.D., M.B.A.					•	
Christine A. Nash, M.B.A.	•	(1)	•			
Paula Soteropoulos (1)			•	(1)		

(1) Chair of committee

Our Audit Committee is composed of Helen M. Boudreau, M.B.A., Robert Hopfner, R.Ph., Ph.D., M.B.A., Ronald Hunt, M.B.A., and Hui Liu, Ph.D., M.B.A., with Ms. Boudreau serving as Chair of the committee. The Board of Directors has determined that each member of the Audit Committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable listing standards of Nasdaq. The Board of Directors has determined that Ms. Boudreau is an "audit committee financial expert" within the meaning of the SEC, regulations and applicable listing standards of Nasdaq. The Audit Committee's responsibilities 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;
- discussing with our independent registered public accounting firm critical audit matters and related disclosures;
- 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;
- reviewing 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, in accordance with Company policy;
- 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.

During the year ended December 31, 2025, the Audit Committee met 4 times. The report of the Audit Committee is included in this Annual Report on Form 10-K under "Audit Committee Report."

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is composed of Wendy K. Chung, M.D., Ph.D., Robert Hopfner, R.Ph., Ph.D., M.B.A., Ronald Hunt, M.B.A. and Christine Nash, M.B.A., with Ms. Nash serving as Chair of the committee. The Board of Directors has determined that each member of the Nominating and Corporate Governance Committee is "independent" as defined under the applicable listing standards of Nasdaq. The Nominating and Corporate Governance Committee's responsibilities 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;
- considering and, if appropriate, 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 our policies and program 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;
- reviewing and reporting to our Board of Directors any actual or potential conflicts of interest of members of our Board of Directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing plans for director succession;
- reviewing and assessing, at least annually, the adequacy of the Nominating and Corporate Governance Committee's charter;
- reviewing and overseeing the Company's initiatives regarding environmental, social and governance matters, including related risks and opportunities, and the Company's public disclosure with respect to such matters; and
- performing, on an annual basis, an evaluation of the performance of the Nominating and Corporate Governance Committee.

The Nominating and Corporate Governance Committee is also responsible for developing and recommending to the Board of Directors criteria for membership on the Board of Directors. During the year ended December 31, 2025, the Nominating and Corporate Governance Committee met 1 time.

Stockholder Proposals and Nominations

Requirements for Stockholder Proposals to be Considered for Inclusion in our Proxy Materials. To be considered for inclusion in the proxy statement for the 2026 annual meeting, stockholder proposals must have been received by our Secretary at our principal executive offices no later than the close of business on December 8, 2025, which is 120 days prior to the date that is one year from last year's mailing date of April 7, 2025.

Requirements for Stockholder Proposals or Director Nominations to be Brought Before an Annual Meeting. Our bylaws provide that, for stockholder nominations to the Board of Directors or other proposals to be considered at an annual meeting, the stockholder must have given timely notice thereof in writing to the Secretary at Rallybio Corporation, 234 Church Street, New Haven, CT 06510. The Nominating and Corporate Governance Committee does not have a written policy regarding stockholder nominations, but has determined that it is the

practice of the committee to consider candidates proposed by stockholders if made in accordance with our bylaws. To be timely for the 2026 annual meeting, although not included in the proxy statement, the stockholder's notice must be delivered to or mailed and received by us not earlier than the close of business on the 120th day nor later than the close of business on the 90th day prior to the anniversary date of the prior year's annual meeting, except that if the annual meeting is set for a date that is not within 30 days before or after such anniversary date, we must receive the notice not later than the close of business on the tenth day following the day on which we first provide notice or public disclosure of the date of the meeting. Assuming the date of our 2025 annual meeting is not so advanced or delayed, stockholders who wish to make a proposal at the 2026 annual meeting must have notified us no earlier than January 13, 2026 and no later than February 12, 2026. Such notice must have provided the information required by our bylaws with respect to each matter the stockholder proposes to bring before the 2026 annual meeting.

Any stockholder who intends to solicit proxies in support of a director nominee other than the Company's nominees must also comply with Rule 14a-19 under the Exchange Act.

Compensation Committee

Our Compensation Committee is composed of Lucian Iancovici, M.D., Christine A. Nash, M.B.A. and Paula Soteropoulos, with Ms. Soteropoulos serving as Chair of the committee. The Board of Directors has determined that each member of the Compensation Committee is "independent" as defined under the applicable listing standards of Nasdaq and meets the independence criteria set forth in Rule 10C-1 under the Exchange Act. The Compensation Committee's responsibilities 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 the 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;
- reviewing 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 purposes 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;
- overseeing our compliance with applicable SEC rules regarding stockholder approval of certain executive compensation matters;
- reviewing and approving all employment contracts 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 and presenting to our Board of Directors management's plans for succession to senior management positions based on guidelines developed and recommended by the Compensation Committee to the full Board of Directors;
- reviewing the Company's strategies, initiatives and programs with respect to the Company's management of human capital resources;
- 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.

Pursuant to its charter, the Compensation Committee has the authority to delegate any of its responsibilities to subcommittees and has the authority to delegate to the Chief Executive Officer the determination of compensation to employees other than executive officers under approved compensation programs to the maximum extent permitted by applicable law. During the year ended December 31, 2025, the Compensation Committee met 5 times.

Compensation Consultant

The Compensation Committee has engaged Pearl Meyer & Partners, LLC ("Pearl Meyer"), as its independent compensation consultant. Pearl Meyer provides analysis and recommendations to the Compensation Committee regarding:

- trends and emerging topics with respect to executive compensation;
- compensation programs for our executive officers, directors and employees; and
- stock utilization and related metrics.

When requested, Pearl Meyer consultants attend meetings of the Compensation Committee, including executive sessions in which executive compensation-related matters are discussed without the presence of management. Pearl Meyer reports to the Compensation Committee and not to management, although Pearl Meyer meets with management for purposes of gathering information for its analyses and recommendations.

In determining to engage Pearl Meyer, the Compensation Committee considered the independence of Pearl Meyer, taking into consideration relevant factors, including the absence of other services provided to the Company by Pearl Meyer, the amount of fees the Company paid to Pearl Meyer as a percentage of Pearl Meyer's total revenue, the policies and procedures of Pearl Meyer that are designed to prevent conflicts of interest, any business or personal relationship of the individual compensation advisors employed by Pearl Meyer with any executive officer of the Company, any business or personal relationship the individual compensation advisors employed by Pearl Meyer have with any member of the Compensation Committee, and any stock of the Company owned by Pearl Meyer or the individual compensation advisors employed by Pearl Meyer. The Compensation Committee has determined, based on its analysis and in light of all relevant factors, including the factors listed above, that the work of Pearl Meyer and the individual compensation advisors employed by Pearl Meyer as compensation consultants to the Compensation Committee has not created any conflicts of interest, and that Pearl Meyer is independent pursuant to the independence standards set forth in the Nasdaq listing standards promulgated pursuant to Section 10C of the Exchange Act.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics for our directors, officers and employees, including our Chief Executive Officer and President and our Chief Financial Officer. A copy of our Code of Business Conduct and Ethics may be accessed free of charge by visiting our website at www.rallybio.com and going to the "Governance" tab under the "Investors" section, or by requesting a copy in writing from our Secretary at our New Haven, Connecticut office. We intend to post on our website any amendment to, or waiver under, a provision of the Code of Business Conduct and Ethics that applies to our directors and certain of our executive officers within four business days following the date of such amendment or waiver.

Environmental, Social and Governance

We endeavor to develop and continuously execute on a scalable strategy that enables the Company to foster its culture and values, create positive social and environmental outcomes, and enhance our business. The Nominating and Corporate Governance Committee has been delegated oversight for such activities by the

Board of Directors. The Company seeks to integrate such considerations into its business in a manner that enhances long-term performance and value for stakeholders.

EXECUTIVE OFFICERS

Below is a list of the names, ages and positions, and a brief account of the business experience of the individuals who serve as our executive officers as of March 6, 2026.

Name	Age	Position
Stephen Uden, M.D.	68	President, Chief Executive Officer; Director
Jonathan I. Lieber, M.B.A.	56	Chief Financial Officer and Treasurer
Steven Ryder, M.D.	75	Chief Medical Officer

EXECUTIVE OFFICER BIOGRAPHIES

Stephen Uden, M.D.'s, biography is included under “Director Biographies” above.

Jonathan I. Lieber, M.B.A., has been Chief Financial Officer and Treasurer of Rallybio since February 2023. Previously, Mr. Lieber, served as the Chief Financial Officer of Applied Genetic Technologies Corporation, a publicly-traded clinical-stage biotechnology company, from September 2021 until November 2022. From December 2018 until September 2021, Mr. Lieber was a Managing Director at Danforth Advisors, a firm providing strategic and operational finance and accounting for life science companies. From July 2015 until December 2018, Mr. Lieber served as Chief Financial Officer of Histogenics Corporation, a publicly traded cell therapy company. Mr. Lieber also served as the Chief Financial Officer of Metamark Genetics, Inc., Repligen Corporation, Xcellerex, Inc., and Altus Pharmaceuticals. Mr. Lieber began his career in healthcare as an investment banker at Salomon Brothers / Salomon Smith Barney and SG Cowen. He has been a member of the board of directors of Decoy Therapeutics, Inc. (Nasdaq: DCOY) since June 2020, Mindwalk Holdings Corp. (Nasdaq: HYFT) since July 2025 and Zola Pharmaceuticals (private) since February 2024. Mr. Lieber received a B.S. in business administration and finance from Boston University and an M.B.A. in finance from New York University’s Leonard N. Stern 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 Pharma Inc. ("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 has been a member of the Board of Directors of MBX Biosciences, Inc. since January 2024 and previously served on the board of directors of Reata Pharmaceuticals, Inc. from July 2022 until September 2023. Dr. Ryder received an M.D. from the Icahn School of Medicine at Mount Sinai.

Contacting the Board of Directors

Stockholders wishing to communicate with the Board of Directors may do so by writing to the Board of Directors or to the non-employee members of the Board of Directors as a group, at:

Rallybio Corporation

234 Church Street

New Haven, CT 06510

Attention: Secretary

The communication must prominently display the legend “BOARD COMMUNICATION” in order to indicate to the Secretary that it is a communication for the Board of Directors. Upon receiving such a communication, the Secretary will promptly forward the communication to the relevant individual or group to which it is addressed. Certain items that are unrelated to the Board’s duties and responsibilities may be excluded, such as spam, junk mail and mass mailings, resumes and other forms of job inquiries, surveys and business solicitations or advertisements. The Secretary will not forward any communication determined in his good faith belief to be frivolous, unduly hostile, threatening, illegal or similarly unsuitable.

Director or Officer Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any legal proceedings as described in Item 401(f) of Regulation S-K in the past ten years.

Item 11. Executive Compensation.

Unless otherwise indicated or the context otherwise requires, references in this section to "Rallybio," the "Company," "we," "us," "our" and other similar terms refer to Rallybio and its subsidiaries.

Executive Compensation

Rallybio's named executive officers for the year ended December 31, 2025 are:

- Stephen Uden, M.D., Chief Executive Officer and President;
- Jonathan I. Lieber, M.B.A., Chief Financial Officer and Treasurer; and
- Steven Ryder, M.D., Chief Medical Officer.

2025 Summary Compensation Table

The following table sets forth the compensation awarded to, earned by or paid to each of our named executive officers for the fiscal years ended December 31, 2025 and December 31, 2024.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)	Option Awards ($)(1)	Nonequity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total
Stephen Uden, M.D.	2025	590,000	—	298,988	259,600	8,380	1,156,968
Chief Executive Officer and President	2024	551,200	—	314,626	248,040	13,800	1,127,666
Jonathan I. Lieber, M.B.A.	2025	478,400	104,688 (2)	118,620	153,088	14,000	868,796
Chief Financial Officer and Treasurer	2024	478,400	—	174,792	172,224	13,800	839,216
Steven Ryder, M.D.	2025	531,227	—	118,620	201,866	14,000	865,713
Chief Medical Officer	2024	531,227	—	174,792	191,242	13,800	911,061

(1) The amounts shown in the "Option Awards" column represent the aggregate grant date fair value of options to purchase shares of our common stock granted to our named executive officers in fiscal years 2025 and 2024 computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 7 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

(2) The amounts shown in the "Stock Awards" column represents the grant date fair value of the performance-based stock units granted in 2025, based on the probable outcome of the performance conditions at grant. The grant date fair value of the award, assuming all performance conditions were satisfied at the maximum level is $104,688. This award was subsequently cancelled and was not outstanding on December 31, 2025.

(3) The amounts shown in the "Nonequity Incentive Plan Compensation" column represent annual bonuses earned with respect to fiscal years 2025 and 2024 under our annual bonus program as described below under "Annual incentive bonuses."

(4) The amounts shown in the "All Other Compensation" column for fiscal years 2025 and 2024 reflect 401(k) plan matching contributions, described below under "Employee and retirement benefits."

Overview

The Compensation Committee of our Board of Directors is responsible for determining the compensation of our named executive officers.

The Compensation Committee has engaged Pearl Meyer, an independent compensation consulting firm, to assist it in evaluating the Company's executive and director compensation practices, including program design, identification of an appropriate peer group for compensation comparison purposes and providing pay benchmarking data. The Compensation Committee has assessed the independence of Pearl Meyer from

management and, on the basis of that assessment and taking into consideration the independence factors that are required to be considered under applicable stock exchange rules, determined that no relationships exist that would create a conflict of interest or that would compromise Pearl Meyer's independence.

Agreements with our named executive officers

In August 2023, Dr. Uden entered into a second amended and restated employment agreement with the Company and our operating company subsidiary, Rallybio, LLC, which sets forth the terms and conditions of Dr. Uden's continued employment with us.

At the time of his commencement of employment, Mr. Lieber entered into an employment agreement with the Company and Rallybio, LLC, which sets forth the terms and conditions of Mr. Lieber's employment with us.

On June 25, 2025, we entered into an employment agreement with Dr. Ryder.

The material terms of the agreements are described below. The terms "cause," "good reason" and "change in control" referred to below are defined in the respective named executive officer's agreement.

The employment agreements for Dr. Uden, Mr. Lieber and Dr. Ryder provide for an initial annual base salary, subject to review for increase by our Board of Directors or the Compensation Committee. Each employment agreement also provides for a target annual bonus as a percentage 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 Directors or the Compensation Committee.

Base Salaries

Effective January 1, 2025, the annual base salary of Dr. Uden was increased from $551,200 to $590,000. The Compensation Committee reviewed pay benchmarking data for the Company's peer group and for the position of Chief Executive Officer and President held by Dr. Uden, and recommended, and the Board of Directors approved, Dr. Uden's 2025 base salary of $590,000. The annual base salaries of Mr. Lieber and Dr. Ryder remained unchanged at $478,400 and $531,227, respectively, for fiscal year 2025.

Annual incentive bonuses

With respect to fiscal year 2025, each of our named executive officers was eligible to receive an annual bonus. For fiscal year 2025, the target bonus amount for Dr. Uden was 55% of his annual base salary. For fiscal year 2025, the target bonus amount for each of Mr. Lieber and Dr. Ryder was 40% of the named executive officer's annual base salary. Annual bonuses for fiscal year 2025 for our named executive officers were based on the attainment of pre-established corporate objectives as determined by the Compensation Committee and the Board of Directors. Following the end of fiscal year 2025, the Compensation Committee and the Board of Directors reviewed the Company's performance against these goals and determined that the performance goals for the named executive officers were achieved at 80% of target for Dr. Uden and Mr. Lieber and 95% of target for Dr. Ryder. Dr. Uden earned a bonus of $259,600, Mr. Lieber earned a bonus of $153,088 and Dr. Ryder earned a bonus of $201,866.

Severance upon termination of employment; change in control; restrictive covenants

Employment Agreements for Dr. Uden and Mr. Lieber. Each of Dr. Uden and Mr. Lieber is entitled to severance payments and benefits in connection with certain qualifying terminations of employment under his respective employment agreement. In connection with the Merger, on March 1, 2026, each of Dr. Uden and Mr. Lieber entered into an amendment to his respective employment agreement to clarify that the Merger will constitute a "change in control" for purposes of each executive's employment agreement. As a result, the enhanced change-in-control severance benefits described below will become payable in the event of a qualifying termination following the closing of the Merger. If the executive officer's employment is terminated by us without cause, or by him for good reason, or as a result of our non-extension of the employment term, he will be entitled to receive (i) any earned and payable, but unpaid, prior year annual bonus (or current year bonus if the termination occurs on the last day of the calendar year), (ii) continued payment of his annual base salary for a period of 12 months following termination and (iii) subject to his timely election of COBRA coverage, payment of a monthly amount equal to the monthly health premiums paid by us on behalf of the executive officer and his eligible dependents immediately prior to termination for 12 months following termination (or, if earlier, until such time as the executive officer ceases to be eligible for COBRA coverage or obtains health coverage from another employer). 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, prior year annual bonus (or current year bonus if the

termination occurs 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.

If the executive officer's employment is terminated by us without cause or by him for good reason, or as a result of our non-extension of the employment term, in each case within the 12-month period following a change in control, which includes the Merger, in lieu of the severance payments and benefits described above, he will be entitled to receive (i) any earned and payable, but unpaid, prior year annual bonus (or current year bonus if the termination occurs on the last day of the calendar year), (ii) an amount equal to 1.5 times the sum of the executive officer's annual base salary and target annual bonus, payable over 18 months following termination, (iii) subject to his timely election of COBRA coverage, payment of a monthly amount equal to the monthly health premiums paid by us on behalf of the executive officer and his eligible dependents immediately prior to termination for 18 months following termination (or, if earlier, until such time as the executive officer ceases to be eligible for COBRA coverage or obtains health coverage from another employer), and (iv) in the case of Mr. Lieber, full vesting of any outstanding and unvested equity awards, the vesting of which is based only on the passage of time, held by Mr. Lieber as of the date of termination. With respect to Dr. Uden, under his second amended and restated employment agreement, any outstanding and unvested equity awards, the vesting of which is based only on the passage of time, held by him as of a change in control will vest in full upon the consummation of the change in control, subject to Dr. Uden's continued employment with us through the date of such change in control.

On March 1, 2026, we and Dr. Uden and Mr. Lieber entered into amendments to their respective employment agreements to clarify that the Merger will constitute a "change in control" for purposes of the agreement. As a result, the enhanced change-in-control severance benefits described above will be triggered in the event of a qualifying termination following the closing of the Merger.

Employment Agreement for Dr. Ryder. On June 25, 2025, we entered into an employment agreement with Dr. Ryder, pursuant to which Dr. Ryder serves as our Chief Medical Officer at an initial annual base salary of $531,227 and is eligible to receive an annual target bonus of up to 40% of his base salary. Dr. Ryder serves for an initial one-year term, which automatically extends for successive one-year terms unless either we or Dr. Ryder elects not to extend the term by giving the other party at least 60 days' notice prior to the end of the current term.

If Dr. Ryder's employment is terminated by us without cause, by him for good reason, or as a result of our non-extension of the employment term, he will be entitled to receive (i) any earned but unpaid annual bonus for a calendar year ending on or preceding the date of termination, (ii) continued payment of his annual base salary for a period of 12 months following termination, and (iii) subject to his timely election of COBRA coverage, payment of a monthly amount equal to the monthly health premiums paid by us on behalf of Dr. Ryder and his eligible dependents for 12 months following termination (or, if earlier, until such time as Dr. Ryder ceases to be eligible for COBRA coverage or obtains health coverage from another employer). If Dr. Ryder's employment is terminated by reason of his death or disability, he will be entitled to receive (i) any earned but unpaid prior year annual bonus and (ii) continued payment of his annual base salary for a period of six months following termination.

If Dr. Ryder's employment is terminated by us without cause, by him for good reason, or as a result of our non-extension of the employment term, in each case within the 12-month period following a change in control, which includes the Merger, in lieu of the severance payments and benefits described above, he will be entitled to receive (i) any earned but unpaid prior year annual bonus, (ii) an amount equal to 1.5 times the sum of his annual base salary and target annual bonus, payable over 18 months following termination, (iii) subject to his timely election of COBRA coverage, payment of a monthly amount equal to the monthly health premiums paid by us on behalf of Dr. Ryder and his eligible dependents for 18 months following termination (or, if earlier, until such time as Dr. Ryder ceases to be eligible for COBRA coverage or obtains health coverage from another employer), and (iv) full vesting of any outstanding and unvested equity awards, the vesting of which is based only on the passage of time, held by Dr. Ryder as of the date of termination.

On March 1, 2026, we and Dr. Ryder entered into an amendment to his employment agreement to clarify that the Merger will constitute a "change in control" for purposes of the agreement. As a result, the enhanced change-in-control severance benefits described above will be triggered in the event of a qualifying termination following the closing of the Merger.

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 the named executive officers 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. Each of the named executive officers is also party to a Confidential Information and Invention Assignment Agreement under which each named executive officer has agreed to a perpetual confidentiality covenant and an assignment of intellectual property covenant.

Better-of Provision. The employment agreements with each of the named executive officers also contain a Section 280G "better of" cutback provision, pursuant to which any payments or benefits that would constitute "parachute payments" within the meaning of Section 280G of the Code will be reduced to the extent necessary to avoid the imposition of the excise tax under Section 4999 of the Code, but only if such reduction would result in a greater after-tax benefit to the named executive officer.

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. We maintain a tax-qualified retirement plan ("401(k) Plan"), for our full-time employees, including our named executive officers. The 401(k) Plan provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual limits provided for in the Internal Revenue Code (the "Code"). We make matching contributions into the 401(k) Plan on behalf of participants, equal to up to 3% of eligible compensation. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. Our 401(k) Plan is intended to be qualified under Section 401(a) of the Code with our 401(k) Plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to our 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from our 401(k) Plan.

Insider Trading Policy

The Company adopted an insider trading policy in connection with the Company's initial public offering in August 2021. The insider trading policy prohibits our officers, directors, and employees from purchasing or selling the Company's securities while in possession of material, nonpublic information, prohibits any hedging, short sales or pledging transactions with respect to the Company's securities by directors, officers and all employees, and includes requirements regarding Rule 10b5-1 plans. In addition, it is the Company's policy to comply with all applicable securities laws when transacting in its own securities.

Clawback

In accordance with the requirements of the Dodd-Frank Act, SEC rules and Nasdaq listing standards, we maintain a clawback policy that requires recoupment of erroneously-awarded incentive compensation received by current or former executive officers in the event we are required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement under applicable securities laws.

Equity compensation

In fiscal year 2025, Dr. Uden was granted an option to purchase 56,711 shares of our common stock under the 2021 Plan, which vests in 48 equal monthly installments over four years, with a grant date fair value of $298,988. Mr. Lieber and Dr. Ryder were each granted an option to purchase 22,499 shares of our common stock under the 2021 Plan, which vests in 48 equal monthly installments over four years, with a grant date fair value of $118,620 each. Each of these options was granted on February 14, 2025 with a per share exercise price of $6.08, the closing price of a share of our common stock on the date of grant (as adjusted for the 1-for-8 reverse stock split effective February 6, 2026). In each case, vesting is generally subject to the named executive officer's continued employment with us through the applicable vesting date.

On January 29, 2025, Mr. Lieber was granted 15,000 performance-based restricted stock units ("PSUs") under the 2021 Plan. The January 2025 PSUs were subsequently cancelled during fiscal year 2025 and were not outstanding as of December 31, 2025.

On February 18, 2026, Mr. Lieber was granted 5,000 PSUs under the 2021 Plan. Of the 5,000 PSUs, 2,500 vested on the date of grant. The remaining 2,500 PSUs (the "CIC PSUs") will vest on the six-month anniversary

of a Change in Control, which includes the Merger, but only if a Change in Control is consummated on or before December 31, 2026, subject to Mr. Lieber's continued employment with the Company from the date of grant through the vesting date. If a Change in Control has not occurred on or before December 31, 2026, the CIC PSUs will be automatically forfeited for no consideration.

The Compensation Committee generally grants options annually to executives and seeks to make such grants on or around the same date each year. Throughout the year, equity awards may be made to new hires or in connection with promotions or other changes in employment, or, as in the case of the February 2026 PSU grant, in connection with a pending transaction. The Compensation Committee does not grant equity-based awards in anticipation of the release of material nonpublic information and does not time the disclosure of material nonpublic information for purposes of affecting the value of executive compensation. In addition, during 2025, we did not grant options to any named executive officer during the four business days prior to or the one business day following the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a Form 8-K that discloses material nonpublic information.

Outstanding Equity Awards at Fiscal 2025 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of the end of fiscal year 2025 (as adjusted for the 1-for-8 reverse stock split effective February 6, 2026):

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Stephen Uden, M.D.	20,000	—	104.00	7/28/2031 (2)
	7,428	322 (1)	120.32	2/7/2032 (3)
	18,952	7,798 (1)	52.00	2/6/2033 (4)
	12,384	14,615 (1)	14.88	2/15/2034 (5)
	11,821	44,890 (1)	6.08	2/14/2035 (6)
Jonathan I. Lieber M.B.A.	21,254	8,745	54.48	2/1/2033 (7)
	6,880	8,119 (1)	14.88	2/15/2034 (8)
	4,690	17,809 (1)	6.08	2/14/2035 (9)
Steven Ryder, M.D.	20,000	—	104.00	7/28/2031 (2)
	7,428	322 (1)	120.32	2/7/2032 (3)
	10,543	4,331 (1)	52.00	2/6/2033 (10)
	6,880	8,119 (1)	14.88	2/15/2034 (8)
	4,690	17,809 (1)	6.08	2/14/2035 (9)

(1) Each stock option vests in 48 equal monthly installments over four years from the date of grant, generally subject to the named executive officer's continued employment with the Company through each applicable vesting date. See "Severance upon termination of employment; change in control; restrictive covenants."

(2) Represents an option to purchase 20,000 shares of our common stock, granted on July 28, 2021, which vested as to 25% of the underlying shares on July 28, 2022. The remaining 75% of the underlying shares vest in 36 equal monthly installments thereafter, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

(3) Represents an option to purchase 7,750 shares of our common stock, granted on February 7, 2022, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

(4) Represents an option to purchase 26,750 shares of our common stock, granted on February 6, 2023, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

(5) Represents an option to purchase 26,999 shares of our common stock, granted on February 15, 2024, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

(6) Represents an option to purchase 56,711 shares of our common stock, granted on February 14, 2025, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

(7) Represents an option to purchase 29,999 shares of our common stock, granted on February 1, 2023, which vested as to 25% of the underlying shares of common stock on February 1, 2024 and vests as to the remaining 75% of the underlying shares of common stock in 36 equal monthly installments thereafter, generally subject to the named executive officer's continued employment with us through the applicable vesting date.

(8) Represents an option to purchase 14,999 shares of our common stock, granted on February 15, 2024, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment with us through the applicable vesting date.

(9) Represents an option to purchase 22,499 shares of our common stock, granted on February 14, 2025, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment with us through the applicable vesting date.

(10) Represents an option to purchase 14,874 shares of our common stock, granted on February 6, 2023, which vests in 48 equal monthly installments, generally subject to the named executive officer's continued employment or service with us through the applicable vesting date.

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, 2025. Dr. Uden did not receive compensation for his service as a director in 2025. His compensation for 2025 is included in the Summary Compensation Table above.

Name	Fees Earned or Paid in Cash ($)[1]	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
Helen M. Boudreau, M.B.A.	55,000	7,228 (4)	—	62,228
Wendy Chung, M.D., Ph.D.	44,000	7,228 (4)	—	51,228
Robert Hopfner, R.Ph., Ph.D., M.B.A.	51,500 (3)	7,228 (4)	—	58,728
Ronald Hunt, M.B.A.	51,500 (3)	7,228 (4)	—	58,728
Lucian Iancovici, M.D.[4]	— (5)	— (5)	—	—
Hui Liu Ph.D., M.B.A.	47,500 (3)	7,228 (4)	—	54,728
Christine A. Nash, M.B.A.	52,600	7,228 (4)	—	59,828
Martin Mackay, Ph.D.	65,000 (3)	7,228 (4)	225,000 (6)	297,228
Paula Soteropoulos	75,000	7,228 (4)	—	82,228

(1) The amounts reported in this column represent cash fees earned in fiscal year 2025, including amounts that certain non-employee directors elected to receive in the form of an option to purchase shares of our common stock as noted by footnote 4. Non-employee directors may elect to receive their annual cash retainer in the form of an option to purchase shares of our common stock, which vests in 12 equal monthly installments on the last day of each month during such calendar year, subject to the director's continued service on our Board of Directors. The grant date of these in-lieu-of-cash options was January 2, 2025 and the number of options granted to each non-employee director was based on their annual fees to be earned and the grant date fair value of the option to purchase shares of common stock computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 7 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

(2) The amounts reported in this column represent the grant date fair value of options to purchase shares of our common stock granted to our non-employee directors in May 2025, computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 7 to our consolidated financial statements included in our Annual Report on Form 10-K for the

fiscal year ended December 31, 2025. As of December 31, 2025, the following non-employee directors held the following number of option awards: Ms. Boudreau — 10,920; Dr. Chung — 11,713; Dr. Hopfner — 20,896; Mr. Hunt — 25,920; Dr. Liu — 20,961; Ms. Nash — 11,200; Dr. Mackay — 96,668; and Ms. Soteropoulos — 11,591. Dr. Iancovici did not hold any stock options as of December 31, 2025. As of December 31, 2025, none of the non-employee directors held unvested restricted stock awards.

(3) The non-employee director elected to receive his or her annual cash retainer in the form of an option to purchase shares of our common stock. The terms of the option to purchase shares of our common stock are described below under “Director compensation policy”.

(4) Represents the grant date fair value of the annual stock option grant to purchase 3,562 shares of our common stock under the 2021 Plan, granted on May 13, 2025 at a per share exercise price of $2.38. The annual option vests in full on the earlier of the first anniversary of the date of grant or the next annual meeting of our stockholders, subject to the director's continued service on the Board of Directors through the vesting date.

(5) Dr. Iancovici declined to accept a stock option grant or a cash retainer in respect of his service as a director in 2025.

(6) Represents consulting fees paid to Dr. Mackay pursuant to his consulting agreement with the Company and Rallybio, LLC, effective January 1, 2025, at a rate of $18,750 per month ($225,000 for the full year).

Director compensation policy

The Board of Directors adopted a non-employee director compensation policy for members of our Board of Directors. In December 2024, the Board of Directors updated the non-employee director compensation policy for compensation payable in 2025. Under the non-employee director compensation policy applicable to 2025 director compensation to the extent not updated as described below, our non-employee directors were and are compensated as follows:

- each non-employee director receives an annual cash fee of $40,000 ($65,000 for the chair of our Board of Directors and $63,500 for the lead director, if applicable);
- each non-employee director who is a member of the Audit Committee receives an additional annual cash fee of $7,500 ($15,000 for the Audit Committee chair);
- each non-employee director who is a member of the Compensation Committee receives an additional annual cash fee of $6,000 ($12,000 for the Compensation Committee chair);
- each non-employee director who is a member of the Nominating and Corporate Governance Committee receives an additional annual cash fee of $4,000 ($8,000 for the Nominating and Corporate Governance Committee chair).
- each non-employee director will annually be granted an option to purchase 3,562 shares (as adjusted for the 1-for-8 reverse stock split effective February 6, 2026) of our common stock under the 2021 Plan on the date of the first meeting of our Board of Directors held after the annual meeting of our stockholders, prorated for non-employee directors initially elected or appointed to our Board of Directors during the 12 months preceding the grant date to reflect the number of months of service during such 12-month period.

Prior to January 1st of any year, a non-employee director may elect to receive his or her annual cash retainer in the form of an option to purchase shares of our common stock, which is expected to vest in 12 equal monthly installments, on the last day of each month during such calendar year, subject to the director’s continued service on our Board of Directors through each applicable vesting date. Four of our non-employee directors made such an election with respect to their 2025 cash retainers.

The stock options granted to our non-employee directors will have a per share exercise price equal to the closing price of a share of our common stock on the date of grant (or the immediately preceding date on which a closing price was reported if there is no closing price on the date of grant) and will expire not later than ten years after the date of grant. The stock option granted to a non-employee director upon the non-employee director’s initial election or appointment to our Board of Directors will vest in three equal annual installments, subject to the director’s continued service on our Board of Directors through each applicable vesting date. The annual stock options granted to our non-employee directors will vest in full on the earlier of the first anniversary of the date of grant or the next annual meeting of our stockholders, subject to the director’s continued service on our Board of Directors through the vesting date. Upon a change in control (as defined in the 2021 Plan (or as such term or similar term is defined in any successor plan)), each initial stock option and each annual stock

option that is then outstanding will vest in full, subject to the director's continued service on our Board of Directors through such change in control.

All cash fees will be paid quarterly, in arrears, or upon the earlier resignation or removal of the non-employee director. The amount of each payment will be prorated for any portion of a calendar quarter that a non-employee director is not serving on our Board of Directors, based on the number of calendar days served by such non-employee director.

Each non-employee director is entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of our Board of Directors and any committee on which he or she serves.

The Compensation Committee reviews and makes recommendations to our Board of Directors regarding the non-employee director compensation arrangements, and the Board of Directors reviews and approves non-employee director compensation. The Compensation Committee considers information regarding director compensation paid at peer companies, including an evaluation of such compensation practices by the Compensation Committee's compensation consultant. In December 2025 following a recommendation from the Compensation Committee, the Board of Directors did not make any changes to the non-employee director compensation policy, applicable to 2026 director compensation, except the annual option to purchase shares of our common stock was increased from an option to purchase 3,562 shares of our common stock to an option to purchase 3,750 shares of our common stock (in each case, as adjusted for the 1-for-8 reverse stock split effective February 6, 2026).

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

On March 6, 2026, Rallybio had 5,289,675 shares of common stock issued and outstanding. The table below shows certain information about the beneficial ownership of Rallybio common stock, as of March 6, 2026, by:

• each of our directors,

• each of our named executive officers, and

• all of our directors and executive officers as a group.

In accordance with U.S. Securities and Exchange Commission ("SEC") rules, we have included in the column "Number of Shares Beneficially Owned" all shares of common stock over which the person has sole or shared voting or investment power as of March 6, 2026, and all shares of common stock that the person has the right to acquire within 60 days after March 6, 2026 through the exercise of any stock options. All shares that a person has a right to acquire within 60 days of March 6, 2026 are deemed outstanding for the purpose of computing the percentage beneficially owned by the person, but are not deemed outstanding for the purpose of computing the percentage beneficially owned by any other person.

Unless otherwise indicated, each person has the sole power (or shares the power with a spouse) to invest and vote the shares of common stock listed opposite the person's name. Where applicable, ownership is subject to community property laws. Our inclusion of shares in this table as beneficially owned is not an admission of beneficial ownership of those shares by the person listed in the table. Except as noted, the address of each stockholder is c/o Rallybio Corporation, 234 Church Street, New Haven, CT 06510.

Name of beneficial owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders:		
FMR LLC (1)	561,798	10.6 %
Entities associated with Viking Global Investors LP (2)	527,871	10.0 %
Entities affiliated with Johnson & Johnson (3)	454,545	8.6 %
Entities affiliated with 5AM Ventures (4)	291,788	5.5 %
Entities affiliated with New Leaf Venture Partners (5)	412,700	7.8 %
Entities affiliated with TPG Inc. (6)	378,551	7.2 %
Entities affiliated with Pivotal bioVenture Partners (7)	300,580	5.7 %
Directors and Named Executive Officers:		
Stephen Uden, M.D. (8)	172,651	3.3 %
Helen M. Boudreau, M.B.A. (9)	10,338	*
Wendy K. Chung, M.D., Ph.D. (10)	8,151	*
Rob Hopfner, R.Ph., Ph.D., M.B.A. (7) (11)	317,914	6.0 %
Ronald M. Hunt, M.B.A. (5) (12)	437,658	8.3 %
Lucian Iancovici, M.D.	—	*
Hui Liu, Ph.D., M.B.A (13)	17,399	*
Martin W. Mackay, Ph.D. (14)	170,260	3.2 %
Christine A. Nash, M.B.A. (15)	7,638	*
Paula Soteropoulos (16)	11,011	*
Jonathan I. Lieber, M.B.A. (17)	43,192	*
Steven Ryder, M.D. (18)	79,672	1.5 %
All executive officers and directors as a group (12 persons) (19)	562,604	10.6 %

*Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Based solely on information contained in a Schedule 13G/A filed with the SEC on March 6, 2026 reporting beneficial ownership of FMR LLC and Abigail P. Johnson. FMR LLC reports sole voting power over 561,798 shares and sole dispositive power over 561,798 shares. Ms. Johnson reports sole dispositive power over 561,798 shares. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

(2) Based solely on information contained in a Schedule 13G/A filed with the SEC on February 17, 2026 reporting beneficial ownership of Viking Global Investors LP, Viking Global Opportunities Parent GP LLC, Viking Global Opportunities GP LLC, Viking Global Opportunities Portfolio GP LLC, Viking Global Opportunities Illiquid Investments Sub-Master LP, and O. Andreas Halvorsen, David C. Ott and Rose S. Shabet (together with Viking Global Investors LP, Viking Global Opportunities Parent GP LLC, Viking Global Opportunities GP LLC, Viking Global Opportunities Portfolio GP LLC, Viking Global Opportunities Illiquid Investments Sub-Master LP, O. Andreas Halvorsen, David C. Ott and Rose S. Shabet (collectively, the “Viking Reporting Persons”). The Viking Reporting Persons report shared voting and dispositive power over 527,871 shares. Viking Global Opportunities Illiquid Investments Sub-Master LP acquired warrants with the right to purchase 416,673 shares. However, the terms of the warrants provide that no holder of warrants shall have the right to exercise any portion of the warrants to the extent that, after giving effect to such issuance after exercise, such holder of warrants (together with its affiliates, any “group” or any other persons whose beneficial ownership could be aggregated with the holders) would beneficially own more than 9.99% of the number of shares immediately following exercise (the “Blocker”). Any holder of warrants, upon notice to the Issuer, may increase or decrease the Blocker, subject to a maximum of 19.99%, but any such increase or decrease will not be effective until the 61st day after such notice is delivered to the Issuer. Accordingly, the amount of shares reported as beneficially owned by the Reporting Persons set forth herein excludes shares that the Reporting Persons do not currently have the right to purchase upon exercise of the warrants held directly by Viking Global Opportunities Illiquid Investments Sub-Master LP due to the Blocker. The

address of each of the Viking Reporting Persons is 600 Washington Boulevard, Floor 11, Stamford, CT 06901.

(3) Based on information contained in a Schedule 13G filed with the SEC on July 30, 2024 reporting beneficial ownership of Johnson & Johnson ("J&J") and Johnson & Johnson Innovation, Inc. ("J&J Innovation" and, together with J&J, the "J&J Reporting Persons"). J&J Innovation is a wholly-owned subsidiary of J&J. The 454,545 shares reported as beneficially owned herein are directly beneficially owned by J&J Innovation. J&J may be deemed to indirectly beneficially own the securities that are directly beneficially owned by J&J Innovation. The J&J Reporting Persons report shared voting and dispositive power over the securities that are directly beneficially owned by J&J Innovation. The address of J&J is One Johnson & Johnson Plaza, New Brunswick, NJ 08901. The address of J&J Innovation is 410 George Street, New Brunswick, NJ 08901.

(4) Based on information contained in a Form 4 filed with the SEC on February 27, 2026, reporting beneficial ownership of 5AM Opportunities I, L.P. ("Opportunities I"), 5AM Opportunities I (GP), LLC ("Opportunities GP"), 5AM Partners V, LLC ("Partners V"), 5AM Ventures V, L.P. ("Ventures V"), Andrew J. Schwab and Scott M. Rocklage (collectively, the "5AM Reporting Persons") and a Form 4 filed with the SEC on March 9, 2023 reporting beneficial ownership of Partners V, Ventures V, Andrew J. Schwab and Scott M. Rocklage. Opportunities I is the beneficial owner of 156,469 shares and Ventures V is the beneficial owner of 135,319 shares. Opportunities GP is the general partner of Opportunities I and may be deemed to have sole voting and dispositive power over the shares held by Opportunities I. Mr. Schwab and Dr. Parmar are each a Managing Member of Opportunities GP and may be deemed to have shared voting and dispositive power over the shares held by Opportunities I. Partners V is the general partner of Ventures V and may be deemed to have sole voting and dispositive power over the shares held by Ventures V. Each of Mr. Schwab, Dr. Parmar and Dr. Rocklage is a Managing Member of Partners V and may be deemed to have shared voting and dispositive power over the shares held by Ventures V. Dr. Parmar, a member of our Board of Directors until October 2024, is a Managing Member at Opportunities GP and Partners V, and may be deemed to have shared voting and dispositive power over all shares held by the 5AM Reporting Persons. Mr. Schwab, Dr. Parmar, Dr. Rocklage, Partners V and Opportunities GP disclaims beneficial ownership over the shares held by Ventures V and Opportunities I, as applicable. The address of each of the 5AM Reporting Persons is 501 2nd Street, Suite 350, San Francisco, California 94107.

(5) Based on information contained in a Schedule 13G/A filed with the SEC on February 6, 2023 reporting beneficial ownership of New Leaf Ventures III, L.P. ("NLV-III"), New Leaf Venture Associates III, L.P. ("NLVA-III"), New Leaf Venture Management III, L.L.C. ("NLVM-III"), New Leaf Biopharma Opportunities II, L.P. ("NL BPO-II"), New Leaf BPO Associates II, L.P. ("NL BPOA-II") and New Leaf BPO Management II, L.L.C. ("NL BPOM-II"), and Mr. Hunt and Vijay Lathi (together with NLV-III, NLVA-III, NKVM-III, NL BPO-II, NL BPOA-II, NL BPOM-II and Mr. Hunt, the "New Leaf Reporting Persons"). Each of NLV-III, NLVA-III and NLVM-III report shared voting and dispositive power over 268,469 shares. Each of NL BPO-II, NL BPOA-II and NL BPOM-II report shared voting and dispositive power over 144,231 shares. Each of Mr. Hunt and Mr. Lathi report shared voting and dispositive power over 412,700 shares. Mr. Hunt, a member of our Board of Directors, is a Managing Director at New Leaf Venture Partners, and may be deemed to have shared voting and dispositive power over all shares held by the New Leaf Reporting Persons. The address of each of NLV-III, NLVA-III, NLVM-III, NL BPO-II, NL BPOA-II, NL BPOM-II, Mr. Hunt and Mr. Lathi is 156 Fifth Avenue, Suite 820, New York, NY 10010.

(6) Based on information contained in a Schedule 13D/A filed with the SEC on March 3, 2026 reporting beneficial ownership of TPG GP A, LLC, David Bonderman, James G. Coulter and Jon Winkelried (collectively, the "TPG Reporting Persons"). The TPG Reporting Persons report shared voting and dispositive power over 378,551 shares. The address of each of the TPG Reporting Persons is c/o TPG Inc., 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102

(7) Based on information contained in a Schedule 13D/A filed with the SEC on February 12, 2024 reporting beneficial ownership of Nan Fung Group Holdings Limited ("NFGHL"), NF Investment Holdings Limited ("NFIHL"), Nan Fung Life Sciences Holdings Limited ("Nan Fung Life Sciences"), Pivotal bioVenture Partners Fund I, L.P. ("Pivotal"), Pivotal bioVenture Partners Fund I G.P., L.P. ("Pivotal GP"), Pivotal bioVenture Partners Fund I U.G.P. Ltd. (the "Ultimate General Partner"), Pivotal Partners Ltd ("Pivotal Partners"), and Pivotal Life Sciences Holdings Limited ("Pivotal Life Sciences," and together with Pivotal, Pivotal GP, Ultimate General Partner and Pivotal Partners, the "Pivotal Entities," and together with NFGHL, NFIHL, Nan Fung Life Sciences, Pivotal, Pivotal GP, the Ultimate General Partner and Pivotal Partners, the "Pivotal Reporting Persons"). The Pivotal Reporting Persons report shared voting

and dispositive power over 300,580 shares. Dr. Hopfner, a member of our Board of Directors, is a General Partner at Pivotal bioVenture Partners, and may be deemed to have shared voting and dispositive power over all shares held by the Pivotal Reporting Persons. The address of each of the Pivotal Entities is 501 Second Street, Suite 200, San Francisco, CA 94107. The address of NFGHL is 23rd Floor, Nan Fung Tower, 88 Connaught Road Central and 173 Des Voeux Road Central, Central, Hong Kong. The address of NFIHL is Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands.

(8) Includes 80,112 shares issuable to Dr. Uden upon the exercise of options held directly by Dr. Uden that are exercisable within 60 days following March 6, 2026.

(9) Includes 7,358 shares issuable to Ms. Boudreau upon the exercise of options held directly by Ms. Boudreau that are exercisable within 60 days following March 6, 2026.

(10) Includes 8,151 shares issuable to Dr. Chung upon the exercise of options held directly by Dr. Chung that are exercisable within 60 days following March 6, 2026.

(11) Includes 17,334 shares issuable to Dr. Hopfner upon the exercise of options held directly by Dr. Hopfner that are exercisable within 60 days following March 6, 2026. See also Footnote 7.

(12) Includes 24,958 shares issuable to Mr. Hunt upon the exercise of options held directly by Mr. Hunt that are exercisable within 60 days following March 6, 2026. See also Footnote 5.

(13) Includes 17,399 shares issuable to Dr. Liu upon the exercise of options held directly by Dr. Liu that are exercisable within 60 days following March 6, 2026.

(14) Consists of (i) 37,251 shares held directly by Dr. Mackay, (ii) 54,562 shares held directly by a limited liability company, of which Dr. Mackay is the managing member, and (iii) 78,452 shares issuable to Dr. Mackay upon the exercise of options held directly by Dr. Mackay that are exercisable within 60 days following March 6, 2026. Dr. Mackay has sole voting and dispositive power over such shares, and is deemed to be the beneficial owner of such shares.

(15) Includes 7,638 shares issuable to Ms. Nash upon the exercise of options held directly by Ms. Nash that are exercisable within 60 days following March 6, 2026.

(16) Includes 8,029 shares issuable to Ms. Soteropoulos upon the exercise of options held directly by Ms. Soteropoulos that are exercisable within 60 days following March 6, 2026.

(17) Includes 39,077 shares issuable to Mr. Lieber upon the exercise of options held directly by Mr. Lieber that are exercisable within 60 days following March 6, 2026.

(18) Includes 54,228 shares issuable to Dr. Ryder upon the exercise of options held directly by Dr. Ryder that are exercisable within 60 days following March 6, 2026.

(19) The beneficial ownership of all directors and executive officers.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

There have been no transactions since January 1, 2024 in which we were a party, the amount involved exceeded or will exceed 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 related person had a direct or indirect material interest, other than compensation arrangements which are described above under the heading “Executive Officer and Director Compensation.”

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 Party Transactions Policy

Our Board of Directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act of 1933, as amended (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.

Director Independence

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors. 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 Nasdaq Stock Market and the rules under the Securities Exchange Act of 1934, as amended (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 Drs. Mackay and Uden, is an "independent director" as defined under applicable rules of the Nasdaq Stock Market. In addition, all members of our Audit Committee satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and all members of our Compensation Committee satisfy 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, and all members of the Nominating and Corporate Governance Committee are "independent" as defined under the applicable listing standards of Nasdaq. 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. Mackay is not independent under these rules because he is a former employee of the Company and is party to a consulting agreement with the Company. Dr. Uden is not an independent director under these rules because he is an employee of Rallybio.

Item 14. Principal Accounting Fees and Services.

We regularly review the services and fees of our independent registered public accounting firm. These services and fees are also reviewed by the Audit Committee on an annual basis. The aggregate fees billed for the fiscal years ended December 31, 2025 and 2024 for each of the following categories of services are as follows:

	Fiscal Year Ended	
Fee Category	**2025**	**2024**
Audit Fees	$ 764,105	$ 832,578
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	3,828	3,828
Total Fees	$ 767,933	$ 836,406

Audit Fees. Audit fees for the fiscal years ended 2025 and 2024 consist of fees billed for professional services provided in connection with the audit of our annual financial statements, the review of our quarterly financial

statements, and audit services that are normally provided by an independent registered public accounting firm in connection with regulatory filings and were $764,105 and $832,578, respectively. The audit fees for the fiscal year ended December 31, 2025 includes fees for professional services provided in connection with our Form S-8 registration statement filed in May 2025, including comfort letters, consents and review of documents filed with the SEC, which totaled approximately $65 thousand. The audit fees for the fiscal year ended December 31, 2024 includes fees for professional services provided in connection with our Form S-3 registration statement filed in May 2024 and our Form S-8 registration statements filed in March 2024, including comfort letters, consents and review of documents filed with the SEC, which totaled approximately $100,000.

Tax Fees. There were no tax fees for the fiscal year ended 2025 and 2024.

All Other Fees. All other fees represent payment for access to Deloitte & Touche LLP online software tools.

The Audit Committee pre-approved all services performed since the pre-approval policy was adopted.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the consolidated financial statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
2.1	Form of Plan of Liquidation and Dissolution (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
2.2	Agreement and Plan of Merger and Reorganization among Rallybio Corporation, Farmington Merger Sub, Inc. and Candid Therapeutics, Inc., dated as of March 1, 2026 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on March 2, 2026)
3.1	Amended and Restated Certificate of Incorporation of Rallybio Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on August 2, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Rallybio Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on January 26, 2026).
3.3	Amended and Restated Bylaws of Rallybio Corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on August 2, 2021).
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on November 14, 2022)
4.3*	Description of Registrant's Securities.
4.4	Registration Rights Agreement, dated April 10, 2024, by and between Rallybio Corporation and Johnson & Johnson Innovation - JJDC, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2024).
10.1+	Asset Purchase Agreement, by and between Rallybio IPA, LLC and Prophylix AS, dated June 28, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).

10.2+	Asset Transfer Agreement, by and between Swedish Orphan Biovitrum AB (PUBL) and IPC Research, LLC, dated March 15, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
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 (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
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 (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.5+	Amendment No. 2 to Product License Agreement, by and between Affibody AB and IPC Research, LLC, dated December 22, 2020 (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.6+	License Agreement, by and between Rallybio IPE, LLC and Kymab Limited, dated as of May 5, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2022).
10.7#	Form of Indemnification Agreement, between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.8#	Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.9#	Form of Non-Qualified Stock Option Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.10#	Non-Qualified Stock Option Award Agreement for Non-Employee Directors under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.11#	Form of Incentive Stock Option Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.12#	Form of Restricted Stock Unit Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.13#	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.14#	Rallybio Corporation 2021 Cash Incentive Plan (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.15#	Rallybio Corporation 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.16#	Second Amended and Restated Employment Agreement, by and between Rallybio, LLC, Rallybio Corporation and Stephen Uden, dated August 1, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2023).
10.17#	Employment Agreement between Rallybio Corporation and Jonathan I. Lieber, dated as of February 1, 2023 (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K (File No. 001-40693), filed with the SEC on March 6, 2023).
10.18#	Employment Agreement, by and between Rallybio, LLC, Rallybio Corporation and Steven Ryder, dated as of June 25, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on June 27, 2025).
10.19#	Form of Equity Adjusted Notice (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).

10.20	Sales Agreement, dated as of August 8, 2022, between Rallybio Corporation and TD Securities (USA) LLC (as successor to Cowen and Company, LLC) (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-266668), filed with the SEC on August 8, 2022).
10.21	Amendment No. 1 to Sales Agreement, dated March 13, 2025, by and between Rallybio Corporation and TD Securities (USA) LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on March 13, 2025).
10.22+	Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion Pharmaceuticals, Inc., Exscientia Ventures I, Inc., Rallybio Corporation and Rallybio IPB, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on November 6, 2025).
19.1*	Company Insider Trading Policy.
21.1	Subsidiaries of Registrant (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K (File No. 001-40693), filed with the SEC on March 12, 2024).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Policy Relating to Recovery of Erroneously Awarded Compensation
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\# 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

RALLYBIO CORPORATION

Date: March 16, 2026

By: /s/ Stephen Uden
Stephen Uden, M.D.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Stephen Uden **Stephen Uden, M.D.**	Chief Executive Officer, President and Director (Principal Executive Officer)	March 16, 2026
/s/ Jonathan I. Lieber **Jonathan I. Lieber**	Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	March 16, 2026
/s/ Martin W. Mackay **Martin W. Mackay, Ph.D.**	Chairman	March 16, 2026
/s/ Helen M. Boudreau **Helen M. Boudreau**	Director	March 16, 2026
/s/ Wendy K. Chung **Wendy K Chung, M.D., Ph.D.**	Director	March 16, 2026
/s/ Robert Hopfner **Robert Hopfner, R.Ph., Ph.D., MBA**	Director	March 16, 2026
/s/ Ronald M. Hunt **Ronald M. Hunt**	Director	March 16, 2026
/s/ Lucian Iancovici **Lucian Iancovici, M.D.**	Director	March 16, 2026
/s/ Hui Liu **Hui Liu, Ph.D.**	Director	March 16, 2026
/s/ Christine A. Nash **Christine A. Nash, MBA**	Director	March 16, 2026
/s/ Paula Soteropoulos **Paula Soteropoulos**	Director	March 16, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Rallybio Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rallybio Corporation and subsidiaries (the “Company”) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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. 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
March 16, 2026

We have served as the Company's auditor since 2018.

RALLYBIO CORPORATION

Consolidated Balance Sheets

(in thousands, except share and per share amounts)	DECEMBER 31, 2025	DECEMBER 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 31,374	$ 13,903
Marketable securities	23,362	51,608
Prepaid expenses and other current assets	6,517	2,330
Total current assets	61,253	67,841
Property and equipment, net	23	115
Operating lease right-of-use assets	175	152
Other assets, noncurrent	810	—
Total assets	$ 62,261	$ 68,108
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 126	$ 278
Accrued expenses	3,791	4,962
Operating lease liabilities	94	154
Deferred revenue	212	848
Total current liabilities	4,223	6,242
Operating lease liabilities, noncurrent	82	—
Deferred revenue, noncurrent	—	212
Total liabilities	4,305	6,454
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized as of December 31, 2025 and 2024; and 5,283,321 and 5,188,743 shares issued and outstanding as of December 31, 2025 and 2024, respectively	4	4
Preferred stock, $0.0001 par value per share; 50,000,000 shares authorized as of December 31, 2025 and 2024; no shares issued or outstanding as of December 31, 2025 and 2024	—	—
Additional paid-in capital	359,932	354,602
Accumulated other comprehensive gain	18	68
Accumulated deficit	(301,998)	(293,020)
Total stockholders' equity	57,956	61,654
Total liabilities and stockholders' equity	$ 62,261	$ 68,108

See accompanying notes to the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)	FOR THE YEAR ENDED DECEMBER 31, 2025	2024
Revenue:		
Collaboration and license revenue	$ 858	$ 636
Total revenue	858	636
Operating expenses:		
Research and development	19,597	41,507
General and administrative	14,325	19,625
Total operating expenses	33,922	61,132
Loss from operations	(33,064)	(60,496)
Other income:		
Interest income	2,189	4,216
Gain on sale of joint venture and other income	22,771	744
Total other income, net	24,960	4,960
Loss before equity in losses of joint venture	(8,104)	(55,536)
Loss on investment in joint venture	874	2,239
Net loss	$ (8,978)	$ (57,775)
Net loss per common share, basic and diluted	$ (1.59)	$ (10.61)
Weighted-average common shares outstanding, basic and diluted	5,629,370	5,443,332
Other comprehensive (loss) gain:		
Net unrealized (loss) gain on marketable securities	(50)	53
Other comprehensive (loss) gain	(50)	53
Comprehensive loss	$ (9,028)	$ (57,722)

See accompanying notes to the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)	COMMON SHARES	COMMON AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	STOCKHOLDERS' EQUITY
December 31, 2023	4,728,674	$ 4	$ 341,410	$ (235,245)	$ 15	$ 106,184
Issuance of common stock from a securities purchase agreement, net of offering costs of $268	454,545	—	5,137	—	—	5,137
Issuance of common stock under the stock purchase plan	7,603	—	62	—	—	62
Issuance of common stock under the stock award plan	241	—	—	—	—	—
Forfeiture of restricted common stock	(2,320)	—	—	—	—	—
Share-based compensation	—	—	7,993	—	—	7,993
Net loss	—	—	—	(57,775)	—	(57,775)
Other comprehensive gain	—	—	—	—	53	53
Balance, December 31, 2024	5,188,743	$ 4	$ 354,602	$ (293,020)	$ 68	$ 61,654
Issuance of common stock under the stock purchase plan	7,258	$ —	$ 16	$ —	$ —	$ 16
Issuance of common stock under the stock award plan	87,320	—	—	—	—	—
Share-based compensation	—	—	5,314	—	—	5,314
Net loss	—	—	—	(8,978)	—	(8,978)
Other comprehensive loss	—	—	—	—	(50)	(50)
Balance, December 31, 2025	5,283,321	$ 4	$ 359,932	$ (301,998)	$ 18	$ 57,956

See accompanying notes to the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Cash Flows

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2025	2024
Cash Flows Used in Operating Activities:		
Net loss	$ (8,978)	$ (57,775)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	92	131
Net accretion of discounts/premiums on debt securities	(573)	(1,612)
Share-based compensation	5,314	7,993
Gain on sale of joint venture	(22,350)	—
Loss on investment in joint venture	874	2,239
Changes in operating assets and liabilities:		
Prepaid expenses, operating right-of-use assets and other current assets	(2,043)	2,724
Accounts payable	(152)	(698)
Accrued expenses and operating lease liabilities	(1,149)	(3,344)
Deferred revenue	(848)	1,060
Net cash used in operating activities	$ (29,813)	$ (49,282)
Cash Flows Provided by Investing Activities:		
Purchases of marketable securities	(17,697)	(48,933)
Proceeds from maturities of marketable securities	46,465	84,425
Proceeds from sale of common stock received from sale of joint venture	20,000	—
Investment in joint venture	(1,500)	(2,000)
Net cash provided by investing activities	$ 47,268	$ 33,492
Cash Flows Provided by Financing Activities:		
Proceeds from the issuance of common stock from a securities purchase agreement	—	5,405
Proceeds from the issuance of common stock under the stock purchase plan	16	62
Payments of offering costs	—	(268)
Net cash provided by financing activities	$ 16	$ 5,199
Net increase (decrease) in cash and cash equivalents	17,471	(10,591)
Cash and cash equivalents—beginning of year	13,903	24,494
Cash and cash equivalents—end of year	$ 31,374	$ 13,903

See accompanying notes to the consolidated financial statements

RALLYBIO CORPORATION

Notes to Consolidated Financial Statements

1. BUSINESS

Rallybio Corporation and subsidiaries ("Rallybio", the "Company", "we", "our", or "us") is a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. The Company's lead program, RLYB116, is a differentiated complement component 5 (“C5”) inhibitor with the potential to treat diseases of complement dysregulation. In addition, RLYB332, a long-acting matriptase-2 ("MTP-2") antibody for the treatment of diseases of iron overload is currently in preclinical development. In 2025, the Company completed a confirmatory pharmacokinetic ("PK") and pharmacodynamic ("PD") study of RLYB116 in healthy volunteers and reported data in the first quarter of 2026. In April 2025, the Company announced the discontinuation of its RLYB212 program for the prevention of fetal and neonatal alloimmune thrombocytopenia ("FNAIT") based on PK data from the Phase 2 clinical trial that demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. In July 2025, the Company entered into a definitive agreement to sell its interest in REV102, an Ectonucleotide Pyrophosphatase/Phosphodiesterase 1 ("ENPP1") inhibitor in preclinical development for the treatment of patients with hypophosphatasia ("HPP"), to a subsidiary of its joint venture partner Recursion Pharmaceuticals, Inc. ("Recursion") (the "JV Sale").

On March 1, 2026, Rallybio entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Candid Therapeutics, Inc., a Delaware corporation (“Candid”), a clinical-stage biotechnology company advancing a leading portfolio of T-cell engager ("TCE") therapeutics for autoimmune diseases, and Farmington Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Rallybio (“Merger Sub”). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into Candid, with Candid surviving as a wholly owned subsidiary of Rallybio (the “Merger” and, together with all of the other transactions contemplated by the Merger, the “Contemplated Transactions”). The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Concurrently with the execution and delivery of the Merger Agreement, certain investors entered into subscription agreements with Candid, pursuant to which such investors have agreed to purchase, immediately prior to the Merger, shares of Candid common stock representing an aggregate commitment of approximately $505.5 million in the concurrent financing (the “Concurrent Financing”). The shares of Candid common stock that are issued in the Concurrent Financing will be or will have the right to be, respectively, converted into shares of Rallybio Common Stock, par value $0.0001 per share ("Rallybio Common Stock"), in the Merger.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the “Effective Time”), (a) each then-outstanding share of common stock or preferred stock of Candid (each such share, a “Candid Share”) (excluding any share described in clauses (b) or (c) below and Candid Shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Rallybio Common Stock calculated in accordance with the Exchange Ratio as set forth in the Merger Agreement (the “Exchange Ratio”), (b) each Candid Share issued in the Concurrent Financing will be converted into the right to receive a number of shares of Rallybio Common Stock calculated in accordance with the Concurrent Financing Exchange Ratio as set forth in the Merger Agreement (the “Concurrent Financing Exchange Ratio”), (c) any Candid Shares held as treasury shares or held or owned by Rallybio, Merger Sub or any subsidiary of Rallybio or Candid immediately prior to the Effective Time will be canceled and shall cease to exist, and no consideration shall be delivered in exchange therefor. Each then-outstanding option to purchase Candid Shares will be converted into an option to purchase Rallybio Common Stock, subject to adjustment as set forth in the Merger Agreement.

Under the Exchange Ratio and Concurrent Financing Exchange Ratio formulas in the Merger Agreement, immediately after the Closing, on a pro forma basis and based upon the number of shares of Rallybio Common Stock expected to be issued in connection with the Merger, pre-Merger equityholders of Candid other than investors in the Concurrent Financing are expected to own approximately 57.55% of the combined company, pre-Merger equityholders of Rallybio are expected to own approximately 3.65% of the combined company and the Investors in the Concurrent Financing are expected to own approximately 38.80% of the combined company (assuming proceeds from the Concurrent Financing of $505.5 million), in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) a valuation for Rallybio of $47.5 million (assuming Rallybio has net cash (“Rallybio Net Cash”) of $37.5 million as of the closing of the

Merger (the “Closing” and such date, the “Closing Date”)), (ii) a fixed valuation for Candid of $750.0 million, and (iii) the relative capitalization of Rallybio and Candid. The percentage of the combined company that each party’s equity holders will own following the Closing is subject to certain adjustments as described in the Merger Agreement, including the amount of the final Rallybio Net Cash at Closing.

Immediately prior to the Effective Time, Rallybio and a rights agent are expected to enter into a Contingent Value Rights Agreement (the “CVR Agreement”), pursuant to which holders of record of certain Rallybio securities as of the close of business on the last business day prior to the day on which the Effective Time occurs will receive one contingent value right (each, a “CVR”) for each outstanding share of Rallybio Common Stock, prefunded warrant, Rallybio restricted stock unit or In the Money Parent Option (as defined in the CVR Agreement) held as of such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to receive their pro rata share of (i) all of the net proceeds (including cash the value of stock to the extent listed on a national exchange, at the time of disposition), if any, received by Rallybio as a result of payments made to Rallybio of any upfront, milestone, royalty and other payments received under any disposition agreement related to Rallybio’s pre-Merger assets (the “Legacy Assets”), and (ii) all of the cash proceeds, if any, received from Recursion under the Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion, Exscientia Ventures I, Inc., Rallybio Corporation and Rallybio IPB, LLC. For a period of one year after the Closing Date, Rallybio will use commercially reasonable efforts to effect the disposition of the Legacy Assets. Such net proceeds will be subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred or other liabilities borne by Rallybio or its affiliates in respect of the Legacy Assets, and losses incurred by Rallybio or its affiliates due to a third-party proceeding in connection with such disposition. If the Merger is completed, the business of Candid will continue as the business of the combined company.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES BASIS OF PRESENTATION AND PRINCIPLES OF CONSOLIDATION

Basis of Presentation—The accompanying consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"), and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). 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").

In the opinion of the Company, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

On February 6, 2026, the Company executed a reverse stock split of its issued and outstanding common stock, par value $0.0001, at a ratio of 1-for-8 with a record date of December 30, 2025 (the “Reverse Stock Split”). All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. See Note 14, "Subsequent Events" for additional details.

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 prior to the Company's initial public offering ("IPO"), for purposes of recording share-based incentive compensation, the fair value of stock options, as well as contracted research and development expenses incurred.

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, 2025 and 2024, the Company incurred a net loss of $9.0 million and $57.8 million, respectively. The loss for the year ended December 31, 2025 included a $23.0 million gain in connection with the JV Sale in 2025. In addition, as of December 31, 2025, the Company had an accumulated deficit of $302.0 million. The Company expects to continue to generate operating losses and negative cash flows in the foreseeable future.

The Company had cash, cash equivalents and marketable securities of $54.7 million as of December 31, 2025. The Company currently expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date these consolidated financial statements are issued. However, the Company does not anticipate that its current cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund any of its product candidates through regulatory approval, and it will need to raise substantial additional capital to complete the development and commercialization of its product candidates, if approved. Rallybio may satisfy its future cash needs through the sale of equity securities, debt financings, corporate collaborations or license agreements, working capital lines of credit, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Collaboration Arrangements—The Company considers the nature and contractual terms of an arrangement to assess whether an arrangement involves a joint operating activity that expose two or more parties to significant risks and rewards dependent on the commercial success of the activity. If the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity, the Company accounts for such arrangement as a collaborative arrangement under ASC 808, *Collaborative Arrangements* ("ASC 808"). ASC 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

For arrangements determined to be within the scope of ASC 808 for certain research and development activities where a collaborative partner is not a customer following the guidance of ASC 606, *Revenue Recognition* ("ASC 606"), the Company accounts for payments due to a collaboration partner as research and development expense and for payments owed to us from our collaboration partner for the reimbursement of research and development costs as a contra-expense in the period such expenses are incurred. The Company classifies payments owed or receivables recorded as other current liabilities and other current assets, respectively, in the Company's consolidated balance sheets. See Note 3, "Collaboration and License Agreements" for additional details.

Asset Acquisitions—The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If this screen criteria is met, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date. See Note 3, "Collaboration and License Agreements" for additional details.

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 RE Ventures I, LLC, a limited liability company ("REV-I"), defined in Note 9, and concluded that it represented a VIE and the Company 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, "Investment in Joint Venture" for additional details.

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* ("ASC 323"). 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 asset on the consolidated balance sheets.

Financial Instruments—The Company's principal financial instruments are comprised of cash, cash equivalents, available for sale marketable securities, accounts payable and accrued liabilities. The carrying value of all financial instruments approximates fair value.

Concentrations of Credit Risk—Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds and marketable securities in government insured financial institutions that are subject to minimal credit and market risk. 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 funds, with original maturities of three months or less at the time of purchase as cash and cash equivalents. The carrying amounts reported on the consolidated balance sheets represent the fair values of cash and cash equivalents.

Marketable Securities—We invest our excess cash balances in highly rated United States ("U.S.") government-backed debt securities and treasuries. We classify our marketable securities as available-for-sale and accordingly, record such securities at fair value. Debt securities with original maturities of greater than 90 days are classified as available-for-sale marketable securities and debt securities with original maturities of less than 90 days from the date of purchase are classified as cash equivalents.

Unrealized gains and losses on our marketable debt securities that are deemed temporary are included in accumulated other comprehensive gain (loss) as a separate component of stockholders' equity. If any adjustment to fair value reflects a significant decline in the value of the security, we evaluate the extent to which the decline is determined to be other-than-temporary and would mark the security to market through a charge to our consolidated statements of operations and comprehensive loss. Credit losses are identified when we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results, with the amount of loss relating to other factors recorded in accumulated other comprehensive gain (loss).

Property and Equipment—Property and equipment are recorded at cost and consist of computer and other equipment, capitalized software, furniture and fixtures and leasehold improvements. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, or for leasehold improvements, over the remaining term of the lease, if shorter. The estimated useful life for each major asset classification are as follows:

Asset Classification	Estimated Useful Life
Computer and other equipment	3 years
Capitalized software	3 years
Furniture and fixtures	6 years
Leasehold improvements	lesser of lease life or useful life

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 the carrying value. No such impairments were recorded during the years ended December 31, 2025 or 2024.

Leases—At the inception of an arrangement, we determine if an arrangement is, or contains, a lease based on the facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease we (i) identify lease and non-lease components, (ii) determine the consideration in the contract, (iii) determine whether the lease is an operating or financing lease; and iv) recognize lease right-of-use ("ROU") assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of fixed, or in substance fixed, lease payments over the expected lease term. When the interest rate implicit in lease contracts is not readily determinable we use our incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

We have elected to combine lease components with non-lease components on our office real estate asset class. Fixed, or in substance fixed, lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed, or in substance fixed, are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within our consolidated statements of operations and comprehensive loss. Some leases include options to extend or terminate the lease and the Company includes these options in the recognition of the Company’s ROU assets and lease liabilities when it is reasonably certain that the Company will exercise such options. We have elected the short-term lease exemption and, therefore, do not recognize a ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Income Taxes—The Company uses the asset and liability method of accounting for income taxes, as set forth in ASC 740, *Accounting for Income Taxes* ("ASC 740"). 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 for the years and jurisdictions in which the temporary differences are expected to be recovered. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company evaluates whether deferred tax assets are more likely than not of being realized in determining whether a valuation allowance is necessary. In making such a determination, the Company considers all available positive and negative evidence, including the future reversals of existing taxable temporary differences, projected future taxable income exclusive of reversing temporary differences and carryforwards, tax-planning strategies, taxable income in prior carryback years if permitted under tax law, and the results from prior years. If the Company determines it is more likely than not, that all or a portion of a deferred tax asset will not be realized a valuation allowance is recorded with a charge to income tax expense. Alternatively, if the Company determines that all or a portion of a deferred tax asset previously not meeting the more likely than not threshold will be realized, the Company reduces its valuation allowance and recognizes a benefit in income tax expense. As of December 31, 2025 and 2024, the Company determined that it is more likely than not that deferred taxes will not be realized and as a result recorded a full valuation allowance against its deferred tax assets.

The Company files a consolidated U.S. federal income tax return and has elected to include all subsidiaries owned more than 80%.

The Company recognizes and measure uncertain tax benefits in accordance with ASC 740 based on a two-step process in which (1) the Company determines whether it is more likely than not that the tax position will be sustained based on the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than fifty percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

Research and Development Expenses—Research and development expenses are comprised of costs incurred in performing research and development activities including personnel salaries, benefits, and share-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.

Stock Warrants—The Company accounts for stock warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and remeasured each balance sheet date thereafter.

Share-Based Compensation—The Company accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation* ("ASC 718"). Generally, share-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. Share-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 share-based compensation in the same period as the forfeitures occur. The Company classifies share-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 estimates the fair value of options granted using the Black-Scholes option pricing model ("Black-Scholes") for stock option grants. The fair value of the Company's common stock is used to determine the fair value of restricted stock awards. Black-Scholes requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate and expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company and in 2024, the Company began to include its historical volatility rate in the computation. The historical volatility is calculated based on a period of time corresponding with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted where the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date corresponding with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

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 liabilities 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.

Future Milestone and Royalty Assets—As part of the JV Sale, the Company received consideration including an estimated $3.0 million in future contingent milestones and royalty payments, which are recognized as a contingent consideration asset within prepaid expenses and other current assets on the consolidated balance sheets. The fair value of this contingent consideration was determined using a model that incorporates significant unobservable inputs based on Company estimates, external data, and management's judgment and forecasts. Key assumptions in the model include the discount rate, the timing of expected cash flows, the probability of achieving the milestone and royalty payments, and projected future net revenues.

The Company periodically reviews the carrying value of the Contingent Consideration when impairment indicators arise and records an impairment loss if the carrying amount materially exceeds the reassessed fair value. Increases in the carrying value are recognized only when contingent gains are realized. Since the contingent payments are tied to Phase 1 clinical study milestones and future royalty payments, the Company believes the likelihood of timely payment by Recursion is remote. See Note 9, "Investment in Joint Venture" for additional details.

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 ("CODM") 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 U.S. See Note 12, "Segments" for additional details.

Basic and Diluted Net Loss Per Share—The Company calculates basic net loss per share by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Basic shares outstanding includes the weighted-average effect of the Company's pre-funded warrants to purchase shares of our common stock requiring little consideration upon exercise. Unvested restricted common shares as of December 31, 2025 and 2024 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 share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include restricted common shares and stock options. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Revenue Recognition—The Company recognizes revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses and related transfer of know-how, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain further research and development services and licenses to the Company's intellectual property. The payment terms of these agreements may include nonrefundable upfront fees, payments based upon the achievement of certain milestones, and additional payments based on product sales derived from the collaboration.

The Company exercises judgment in assessing those promised goods and services that are distinct and thus representative of performance obligations. To the extent the Company identifies multiple performance obligations in a contract or group of contracts signed together, the Company must develop assumptions that require judgment to determine the estimated standalone selling price for each performance obligation in order to allocate the transaction price among the identified performance obligations. The transaction is allocated on a relative standalone selling price basis.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are reassessed at each reporting period as required.

The Company then recognizes revenue in the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligations and recognizes revenue over the satisfaction of the performance obligations.

Restructuring—The Company accounts for restructuring charges in accordance with ASC Subtopic 420-10, *Exit or Disposal Cost Obligations*. The charges related to the workforce reductions are cash-based expenditures related primarily to severance and benefit payments, with such amounts reflected in the Company's consolidated statements of operations and other comprehensive loss. See Note 13, "Restructuring" for additional details.

Recently Adopted Accounting Pronouncements—In December 2023, the FASB issued, ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* ("ASU 2023-09") which establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. The ASU is effective for public business entities for fiscal years beginning on or after December 15, 2024 with early adoption permitted. The amendments in ASU 2023-09 were early adopted by the Company on a prospective basis. There was no material impact to the Company's financial statements as a result of adopting ASU 2023-09. See Note 8, "Income Taxes" for additional detail.

In May 2025, the FASB issued ASU 2025-03, Business Combinations (Topic 805) and Consolidation (Topic 810): *Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity* ("ASU 2025-03"), which revises current guidance for determining the accounting acquirer for a transaction effected primarily by exchanging equity interests in which the legal acquiree is a variable interest entity that meets the definition of a business. The amendments require that an entity consider the same factors that are currently required for determining which entity is the accounting acquirer in other acquisition transactions. The Company early adopted this ASU on a prospective basis as of October 1, 2025. There was no material impact to the Company's financial statements as a result of adopting ASU 2025-03.

Recently Issued Accounting Pronouncements—In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): *Disaggregation of Income Statement Expenses (*"ASU 2024-03"). This ASU requires public entities to disclose additional transparency on certain costs and expenses. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company has chosen not to early adopt this standard and is currently evaluating the potential impact of adopting this standard on its consolidated financial statements.

3. COLLABORATION AND LICENSE AGREEMENTS

Johnson & Johnson Collaboration

In April 2024, the Company entered into a two-year collaboration agreement (the "J&J Collaboration Agreement") with Johnson & Johnson, through its wholly-owned subsidiary, Momenta Pharmaceuticals, Inc. (“J&J”) to facilitate the advancement of research into products to address unmet needs relating to FNAIT.

In April 2025, the Company announced that RLYB212 Phase 2 PK results did not achieve target concentrations, including the minimum target concentration required for efficacy, and that the Company would discontinue its RLYB212 program for the prevention of FNAIT. The Company will continue to follow any previously screened Phase 2 participant who was also eligible to enroll in the multinational FNAIT natural history study, in accordance with the study's protocol.

Pursuant to the J&J Collaboration Agreement, the Company received an upfront payment of $0.5 million from J&J for the information dissemination and data provision services under the agreement. The J&J Collaboration Agreement provides that the Company is eligible for payments upon the achievement of certain screening-related events, however, the Company has discontinued screening and enrollment in both the FNAIT natural history study and the RLYB212 Phase 2 clinical trial.

The Company evaluated the agreement and determined it was within the scope of ASC 606. The Company determined there were performance obligations as follows:

(1) Data collection & submission revenue – derived from Rallybio’s ongoing management of the studies including the maintenance of a minimum site footprint, the license to utilize, and timely, semi-annual submission of the anonymized data, in the required formats.

(2) Dissemination of J&J materials & participant revenue – derived from Rallybio’s dissemination of content, information or materials related to the J&J-Sponsored Studies that are developed by J&J and are provided by Rallybio for the purpose of disseminating such content, information, or materials to staff at Rallybio study sites to provide to potential eligible participants regarding J&J’s independent study.

In April 2024, the Company also entered into a securities purchase agreement (the "JJDC Securities Purchase Agreement") with Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"). Under the terms of the JJDC Securities Purchase Agreement, JJDC made an equity investment purchasing 454,545 shares of common stock with a par value of $0.0001 per share for a share purchase price of $14.56 per share which includes a 10% premium for an aggregate purchase price of $6.6 million. The JJDC Securities Purchase Agreement contains provisions related to the registration of the shares and the restriction on the sale or transfer of the shares for a period of time. The Company determined the J&J Collaboration Agreement and the JJDC Securities Purchase Agreement represented combined agreements. In accordance with ASC 606 and ASC 820, total consideration of $1.2 million for the shares of common stock from the JJDC Securities Purchase Agreement, which represents the premium of $0.7 million and discount for lack of marketability of $0.5 million, has been allocated to revenue and will be recognized over the two year expected performance period.

The Company valued the common stock issued to JJDC, in connection with the JJDC Securities Purchase Agreement at fair value. The resulting fair value of $5.4 million was determined by applying the discount due to lack of marketability during the registration and lock-up period to the public trading price of the common stock, which is a Level 1 input, on the date of sale. The Company determined the value of the lack of marketability during the registration and lock-up period by utilizing put option models, which are considered Level 3 inputs. Such option models included the Company’s historical volatility of 113.2% and the risk-free rate of 5.28% based on U.S. Treasury bond rates, as key inputs.

The Company recognized $0.8 million and $0.6 million, respectively, in revenue during the years ended December 31, 2025 and 2024, related to data collection and data submission with the identified performance obligations, and the premium and discount allocated to revenue from the sale of the common stock to JJDC.

The remaining revenue is included in deferred revenue on the Company's consolidated balance sheets as of December 31, 2025, and will be recognized as the performance obligations are satisfied.

The Company determined that the J&J Collaboration Agreement is not in the scope of ASC 808, *Collaborative Arrangements*.

Asset Acquisition

In May 2022, we obtained worldwide exclusive rights to RLYB331, with Kymab Limited ("Sanofi") a preclinical antibody. In 2024, we re-engineered RLYB331 to extend its half-life and renamed the program RLYB332. We believe RLYB332 has the potential to address a significant unmet need for patients with severe anemias with ineffective erythropoiesis and iron overload, including beta thalassemia and a subset of lower risk myelodysplastic syndromes ("MDS"). Under the terms of the license agreement, we made an upfront payment to Sanofi of $3.0 million in the second quarter of 2022 for the exclusive license to KY1066. We could also be required to pay up to an aggregate of $43.0 million in development and regulatory milestones and up to an aggregate of $150.0 million in commercial milestones for a product in its first indication, plus tiered low-to-mid double digit percentages of such milestone amounts for up to three additional indications, and mid to high single digit royalties on net sales.

The license was accounted for as an asset acquisition as substantially all of the fair value of the asset acquired was concentrated in a single asset and thus the acquisition was deemed not to be a business combination. The acquired license rights represent an IPR&D asset that was determined to have no alternative future use. Accordingly, the Company recorded an IPR&D charge of $3.1 million to research and development expense, including transaction costs associated with this asset acquisition of $0.1 million, in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. The Company did not record an IPR&D charge for the years ending December 31, 2025 and 2024 and did not achieve any milestones related to the terms of the license agreement.

AbCellera Collaboration

In December 2022, the Company entered into a multi-year, multi-target collaboration with AbCellera Biologics ("AbCellera") to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. Under the terms of the agreement, AbCellera and Rallybio will co-develop and share the development costs of up to five rare disease therapeutic targets, which will be chosen together by both companies. At the point one party in the collaboration opts-out of future co-development cost sharing, that party will be entitled to a share of future profit sharing from commercialization of the collaboration target, dependent on the proportion of their co-development contributions compared to the total development costs of a target as defined within the agreement. The agreement also has defined profit sharing floors that correspond to the stage of development at the time a collaboration party opts-out of co-developing a target.

The Company concluded that the agreement with AbCellera will be accounted under the scope of ASC 808 as both parties will actively participate in joint operating activities and are exposed to significant risks and rewards that depend on the commercial success of those activities. Under ASC 808, certain transactions between collaborative arrangement participants should follow the accounting for revenue under ASC 606 when the collaborative arrangement participant is a customer.

The Company determined that co-development arrangement as defined in our agreement with AbCellera does not meet the definition of a customer as defined by ASC 606. As a result, these activities will be accounted for as research and development costs. Payments due because of the co-development will be recorded as research and development expense in the period such expenses are incurred and for payments owed to us from our collaboration partner for the reimbursement of research and development costs will be recorded as a contra-research and development expense in the period such expenses are incurred. Costs related to the AbCellera collaboration were $0.4 million for the year ended December 31, 2024. There were no costs related to the AbCellera collaboration for the year ended December 31, 2025.

4. MARKETABLE SECURITIES

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and fair value of our marketable securities by type of security as of December 31, 2025 and 2024 was as follows:

		DECEMBER 31, 2025			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Cash and cash equivalents	Level 1	$ 6,695	$ —	$ —	$ 6,695
U.S. treasury securities	Level 1	19,212	17	—	19,229
U.S. government agency securities	Level 2	4,630	1	—	4,631
		$ 30,537	$ 18	$ —	$ 30,555

		DECEMBER 31, 2024			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Money market funds	Level 1	$ 8,705	$ —	$ —	$ 8,705
U.S. treasury securities	Level 1	34,316	54	(15)	34,355
U.S. government agency securities	Level 2	17,224	32	(3)	17,253
		$ 60,245	$ 86	$ (18)	$ 60,313

The fair values of marketable securities by classification on the consolidated balance sheets as of December 31, 2025 and 2024 was as follows:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Cash and cash equivalents	$ 7,193	$ 8,705
Marketable securities	23,362	51,608
	$ 30,555	$ 60,313

The fair values of available-for-sale debt securities as of December 31, 2025 and 2024, by contractual maturity, are summarized as follows:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Due in one year or less	$ 30,555	$ 51,357
Due after one year through two years	—	8,956
	$ 30,555	$ 60,313

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2025 and 2024 was $0.7 million and $10.4 million, respectively. As of December 31, 2025 and 2024, we did not have any investments in a continuous unrealized loss position for more than twelve months. As of December 31, 2025, the Company believes that the cost basis of our available-for-sale debt securities is recoverable. No allowance for credit losses was recorded as of December 31, 2025 and 2024.

5. LEASES

The Company has an operating lease for approximately four thousand five hundred square feet of corporate office space. The weighted-average remaining lease term as of December 31, 2025 was 1 year, 9 months. The weighted-average discount rate utilized on our operating lease liabilities as of December 31, 2025 was 9.00%.

Operating leases are included in operating lease ROU assets, operating lease liabilities, and operating lease liabilities, noncurrent in our consolidated balance sheets as of December 31, 2025 and 2024.

The following table summarizes the presentation of the Company's operating lease as presented on the consolidated balance sheets:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Assets:		
Operating lease right-of-use assets	$ 175	$ 152
Liabilities:		
Operating lease liabilities	$ 94	$ 154
Operating lease liabilities, noncurrent	82	—
Total operating lease liabilities	$ 176	$ 154

Future minimum lease payments from December 31, 2025 until the expiration of the operating lease are as follows:

(in thousands)	
2026	$ 106
2027	84
Thereafter	—
Total lease payments	190
Less: imputed discount rate	(14)
Carrying value of operating lease liabilities	$ 176

The Company incurred $0.2 million in operating lease rent expense for both years ended December 31, 2025 and 2024. Lease payments made were $0.2 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively, with such amounts reflected on the consolidated statements of cash flows in operating activities.

6. BALANCE SHEET COMPONENTS

Property and Equipment—
Property and equipment consisted of the following as of December 31, 2025 and 2024:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Computer and other equipment	$ 191	$ 191
Capitalized software	89	89
Furniture and fixtures	76	151
Leasehold improvements	147	338
Total property and equipment	503	769
Less: accumulated depreciation	(480)	(654)
Total property and equipment—net	$ 23	$ 115

Depreciation expense totaled $0.1 million for both years ended December 31, 2025 and 2024.

Prepaid Expenses and Other Assets—
Prepaid expenses and other assets consisted of the following as of December 31, 2025 and 2024:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Research and development	$ 3,372	$ 697
Insurance	409	424
Other prepaids	219	214
Other current assets	2,517	995
	$ 6,517	$ 2,330

Accrued Expenses—
Accrued expenses consisted of the following as of December 31, 2025 and 2024:

(in thousands)	DECEMBER 31, 2025	DECEMBER 31, 2024
Research and development	$ 394	$ 1,197
Compensation and related expenses	2,334	3,095
Professional fees	1,039	510
Other	24	160
	$ 3,791	$ 4,962

7. STOCKHOLDERS' EQUITY

Common Stock
In April 2024, the Company entered into the JJDC Securities Purchase Agreement, pursuant to which the Company sold to JJDC, in an unregistered offering, 454,545 shares of its common stock, at a price of $14.56 per share, which represents a 10% premium on the Company's closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses.

The Company had 200,000,000 shares of common stock authorized as of December 31, 2025 and 2024, of which 5,283,321 and 5,188,743 shares were issued and outstanding as of December 31, 2025 and 2024, respectively.

Preferred Stock
The Company had 50,000,000 shares of preferred stock authorized as of December 31, 2025 and 2024, of which no shares were outstanding as of December 31, 2025 and 2024.

Pre-Funded Warrants
In connection with the November 2022 follow-on offering, the Company entered into an agreement with certain investors for pre-funded warrants in lieu of common stock to purchase up to an aggregate of 416,673 shares of common stock at a price of $47.9992, which represents the per share public offering price at the November 2022 follow-on offering for common stock less a $0.0008 per share exercise price for each pre-funded warrant.

The Company may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder's election upon 61 days' notice to the Company subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99%.

The Company's pre-funded warrant is a freestanding instrument that does not meet the definition of a liability pursuant to ASC 480 and does not meet the definition of a derivative pursuant to ASC 815. The pre-funded warrant is indexed to the Company's common stock and meets all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the pre-funded warrant was classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. All of the pre-funded warrants related to our November 2022 follow-on offering remain outstanding and unexercised as of December 31, 2025.

Share-based Compensation

Share-based compensation is comprised of the Company's stock options, restricted stock awards, restricted stock units and shares issued pursuant to the employee stock purchase plan, and is classified in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 and was as follows:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands)	2025	2024
Research and development	$ 2,250	$ 3,269
General and administrative	3,064	4,724
	$ 5,314	$ 7,993

2021 Equity Incentive Plan

In 2021, the board of directors adopted the Rallybio Corporation 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan initially reserved 680,043 shares of the Company's common stock that have been issued in respect of outstanding equity awards granted prior to the registrant's IPO and for future issuances of shares to employees, directors and consultants in the form of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on the Company's common stock. Dividend equivalents may also be provided in connection with awards under the 2021 Plan. The share pool will automatically increase on January 1st of each year until 2031 by the lesser, of (i) five percent of the number of shares of the Company's common stock outstanding as of such date and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. On January 1, 2025 and January 1, 2024, the 2021 Plan share pool was automatically increased by 259,438 and 236,434 shares, respectively. As of December 31, 2025, the total number of shares of the Company's common stock that were issuable under the 2021 Plan was 1,257,573 shares, of which 590,690 shares remained available for future issuance.

The following table summarizes stock option activity for the year ended December 31, 2025:

Stock Options	Number of Option Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding stock options at December 31, 2024	529,342	$ 62.83	7.8	$ —
Granted	224,179	$ 5.87		
Forfeited	(51,758)	$ 32.54		
Expired	(73,483)	$ 76.34		
Exercised	—	$ —		
Outstanding at December 31, 2025	628,280	$ 43.42	7.6	$ 89
Exercisable stock options at December 31, 2025	399,047	$ 58.72	7.1	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock. Stock options outstanding with an exercise price below the closing price as of December 31, 2025 had an intrinsic value of approximately $89 thousand based on a common stock fair value of $5.49 per share, which was the closing price of the Company's common stock on December 31, 2025. Stock options outstanding and exercisable with an exercise price above the closing price as of December 31, 2025 are considered to have no intrinsic value. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $4.92 per share and $11.78 per share, respectively. As of December 31, 2025, there was unrecognized share-based compensation expense related to nonvested stock options of $2.8 million, which the Company expects to recognize over a weighted-average period of approximately 1.9 years.

The fair value of the stock options granted during the years ended December 31, 2025 and 2024 was determined using the Black-Scholes option pricing model with the following assumptions:

	FOR THE YEAR ENDED DECEMBER 31,	
	2025	2024
Expected volatility	91.88% - 119.61%	89.41% - 94.48%
Expected term (years)	5.27 - 6.02	5.50 - 6.02
Risk free interest rate	4.03% - 4.39%	3.93% - 4.35%
Expected dividend yield	—	—
Exercise price	$2.38 - $7.60	$14.88 - $19.20

A summary of the status of the Company's nonvested restricted common stock awards at December 31, 2025 and changes during the year ended December 31, 2025 was as follows:

Restricted Stock Awards	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested restricted common stock awards at December 31, 2024	2,687	$ 31.76
Granted	—	$ —
Vested	(2,687)	$ 31.76
Forfeited	—	$ —
Nonvested restricted common stock awards at December 31, 2025	—	$ —

As of December 31, 2025, there was no unrecognized share-based compensation expense related to nonvested restricted common stock awards.

A summary of the status of the Company's nonvested restricted common stock units at December 31, 2025 and changes during the year ended December 31, 2025 was as follows:

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested restricted common stock units at December 31, 2024	133,069	$ 18.89
Granted	59,500	$ 5.96
Forfeited	(66,646)	$ 12.34
Vested	(87,320)	$ 19.18
Nonvested restricted common stock units at December 31, 2025	38,603	$ 9.60

As of December 31, 2025, there was unrecognized share-based compensation expense related to nonvested restricted common stock units of $0.3 million, which the Company expects to recognize over a weighted-average period of approximately 2.4 years.

2021 Employee Stock Purchase Plan

In connection with the Company's IPO, the board of directors adopted the Rallybio Corporation 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which initially reserved 36,415 shares of the Company's common stock for future issuances under this plan. The share pool will automatically increase on January 1st of each year from 2022 to 2031 by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date (ii) 72,831 shares of the Company's common stock, and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. The 2021 ESPP share pool did not increase on January 1, 2025 or January 1, 2024. As of December 31, 2025, the total number of shares of the Company's common stock available for future issuance under the 2021 ESPP was 94,281 shares. During the years ended December 31, 2025 and 2024, the Company issued 7,258 and 7,603 shares, respectively, of the Company's common stock under the 2021 ESPP.

The 2021 ESPP allows eligible participants to purchase shares of the Company's common stock through authorized payroll deductions. The purchase price of the shares will not be less than 85% of the lower of the fair market value the Company's common stock on the first day of an offering or on the date of the purchase.

For the years ended December 31, 2025 and 2024, the total share-based compensation for the 2021 ESPP was $16 thousand and $0.1 million, respectively.

8. INCOME TAXES

The following table summarizes income (loss) before income taxes:

(in thousands)	2025
Domestic	$ (8,978)
Foreign	—
Total	$ (8,978)

The Company had no income tax expense (benefit) for the years ended December 31, 2025 and 2024.

The Company's effective tax rate for the period ended December 31, 2025 was 0.0%. For the period ended December 31, 2025, the primary drivers of the variance from the statutory rate were state taxes, research & development tax credits, stock based compensation, and valuation allowance.

The following is a reconciliation from the Company's statutory rate to the effective tax rate reported in the financial statements:

	2025	
(in thousands)	Amount	Rate
Statutory federal income tax rate	$ (1,885)	21.0%
Tax credits (federal):		
Orphan drug credit	(1,331)	14.8 %
Other	(231)	2.6 %
Valuation allowance	2,203	(24.5) %
Non-deductible or non-taxable items:		
Share-based compensation	1,227	(13.7) %
Other adjustments	17	(0.2%)
Effective income tax rate	$ —	0.0%

The Company’s effective income tax rates are different from the federal statutory tax rates in 2024 predominantly due to the valuation allowance, tax credits, and state taxes. A reconciliation of the effect of applying the federal statutory rate to the net loss and effective income tax rate are as follows:

	2024
U.S. federal statutory income tax rate	21.0%
State income taxes, net of federal income tax benefit	5.4%
Tax credits	10.7%
Other	(2.9)%
Valuation allowance	(34.2)%
Effective income tax rate	0.0%

The tax effect of temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases that give rise to deferred tax assets and liabilities are as follows at December 31, 2025 and 2024:

(in thousands)	2025	2024
Net operating loss carryforwards	$ 50,322	$ 45,973
Amortization	1,775	1,341
Section 174 capitalization	19,947	22,479
Research and development tax credits	25,701	24,047
Share-based compensation	2,405	2,654
Other	301	1,476
Total deferred tax assets	100,451	97,970
Valuation allowance	(100,451)	(97,970)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company's federal and state post-apportioned net operating loss carryforwards are approximately $183.3 million and $181.6 million, respectively. Of the federal amount, $183.3 million will have an indefinite carryforward period. Of the state post-apportioned amount, $181.6 million have a limited carryforward period and will begin to expire in 2038.

As of December 31, 2025, the Company's federal and state research and development credit carryforwards are approximately $25.0 million and $0.9 million, respectively. All tax credits have a limited carryforward period and will begin to expire in 2038.

After weighing all available positive and negative evidence, the Company has recorded a valuation allowance of approximately $100.5 million and $98.0 million as of December 31, 2025 and 2024, respectively. The Company increased the valuation allowance by $2.5 million and $19.7 million for the years ended December 31, 2025 and 2024, respectively.

The Company is subject to income tax in multiple jurisdictions, including federal, states, and city jurisdictions. The Company has federal, state, and city income tax returns that are open to examination from 2022, 2023, and 2024 forward, respectively. In addition, the utilization of tax carryforwards, from periods prior to those previously mentioned may also be audited by the taxing authorities once utilized.

As a result, the Company continuously monitors its current and prior filing positions in order to determine if any unrecognized tax positions need to be recorded. The analysis involves considerable judgement and is based on the best information available. As of December 31, 2025 and 2024, the Company has no unrecognized tax benefits.

The Company has not accrued any interest expense or penalties related to the unrecognized tax benefits for the respective periods ended December 31, 2025 and 2024.

The Company has made no income tax payments and received no income tax refunds during the respective periods ended December 31, 2025 and 2024. All payments made to taxing authorities were for non-income based tax liabilities and are outside the scope of ASC 740.

The One Big Beautiful Bill Act (the "OBBBA") was enacted on July 4, 2025. The Company has evaluated whether the OBBBA has a material impact on its 2025 financial statements. The only provision of the OBBBA that impacts the Company’s income tax accounting under Accounting Standards Codification 740 is the new Internal Revenue Code of 1986, as amended, Section 174A ("Section 174A"), which permanently allows taxpayers to fully expense domestic research or experimental ("R&E") expenditures paid or incurred in taxable years beginning after December 31, 2024. The requirement to capitalize foreign expenses under Internal Revenue Code Section 174 over 15 years has not changed. On August 28, 2025, the Internal Revenue Service released procedural guidance (Rev. Proc. 20;/.25-28) for implementing Section 174A and related elections for domestic R&E. Transition rules provide taxpayers with options to account for any remaining unamortized domestic R&E expenditures paid or incurred in taxable years beginning after December 31, 2021, and before January 1, 2025. Taxpayers may continue to amortize such unamortized amounts over the remaining five-year period; alternatively, they may elect to deduct any remaining unamortized domestic R&E expenditures either entirely in the first tax year beginning after December 31, 2024, or ratably over two taxable years (e.g., 2025 or

ratably in 2025 and 2026). The company has decided it will elect to continue to amortize previously capitalized and unamortized domestic R&E expenditures over the remaining five-year period. As of December 31, 2024, the company had approximately $41.4 million of remaining unamortized domestic research and development expenditures, representing approximately $11.4 million of its deferred tax assets. As of December 31, 2025, the company had approximately $25.5 million of remaining unamortized domestic research and development expenditures, representing approximately $7.0 million of its deferred tax assets.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 and Section 383 of the Code, and corresponding provisions of state law, due to ownership changes that may have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income and tax liabilities. In general, an ownership change, as defined by Section 382 of the Code, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 5% over a three-year period.

The Company completed a Section 382 study and concluded that it underwent an ownership change as defined by the Code during the year ended December 31, 2021. The Company does not currently believe that the annual limitation will result in the expiration of any net operating losses or research and development tax credit carryforwards before utilization. Additional ownership changes which may have occurred after December 31, 2021 and any future ownership changes may limit our ability to utilize remaining tax attributes. Any carryforwards that will expire prior to utilization as a result of such additional limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

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.

9. INVESTMENT IN JOINT VENTURE

In July 2025, the Company entered into the ENPP1 Purchase Agreement to sell its interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Buyer (a subsidiary of its joint venture partner Recursion). In connection with the JV Sale, the Company received compensation in the form of Recursion common stock (which is a non-cash investing activity). The Company subsequently sold the Recursion common stock for cash proceeds of $20.0 million in the third quarter of 2025 which included $7.5 million from an upfront payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. The Company is eligible to receive a $5.0 million milestone cash payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by REV-I. The Company may also be eligible to receive certain payments in the event of Recursion's sale of the REV102 program.

The Company evaluated the JV Sale under ASC 860, *Transfers and Servicing of Financial Assets* ("ASC 860"). Based on the Company's evaluation of the JV Sale under ASC 860, the Company recognized a gain from the sale of its equity interests in REV102 of $22.4 million, based on the excess of the total net consideration allocated to the sale of the Company's equity interests (based on relative fair value) of $23.0 million over the carrying value of the equity interests sold of $0.6 million. The total net consideration of $23.0 million included cash received of $20.0 million, plus an estimated $3.0 million representing the fair value of the future milestone payments and future royalties (which is a non-cash investing activity).

The contingent consideration was initially measured at fair value using a probability based present value model of the risk-adjusted estimated cash flows, with a discount rate of 15.4%. This valuation model relied on significant unobservable inputs (level 3 inputs) based on management's estimates, which were informed by external data, judgment, and forecasts. Key assumptions included the probability of achieving the milestone and royalties, timing of cash flows, discount rate, and forecasted net revenues. The fair value of the contingent consideration is a non-recurring fair value measurement and is recorded as other assets and other assets, non-

current on the Company's consolidated balance sheets and as gain on sale of joint venture and other income within the Company's consolidated statements of operations and comprehensive loss.

Prior to the JV Sale, the Company, through one of its wholly-owned subsidiaries, had a 50% interest of the joint venture entity, REV-I. For the years ended December 31, 2025 and 2024 the Company funded $1.5 million and $2.0 million, respectively, associated with the Company's commitment and its share of REV-I development costs. The Company did not provide any additional financial support outside of capital contributions to REV-I during the years ended December 31, 2025 and 2024. However, in connection with the joint venture, the Company provided certain scientific and finance and accounting related support which was reimbursed by REV-I to the Company and included in other income on the consolidated statements of operations and comprehensive loss. For the years ended December 31, 2025 and 2024, the Company recorded $0.3 million and $0.7 million, respectively, related to such support. Prior to the JV Sale, the Company held a 50% interest in the joint venture and based on management's analysis, the Company was not the primary beneficiary of REV-I and accordingly, the entity was not consolidated in the Company's consolidated financial statements.

For the years ended December 31, 2025 and 2024, the Company recorded its allocable share of REV-I's losses, which totaled $0.9 million and $2.2 million, respectively, as a loss on investment in joint venture in the consolidated statements of operations and comprehensive loss. After recognition of its share of losses for the period, the carrying value and maximum exposure to risk of the REV-I investment there was no carrying value remaining on the REV-I investment as of December 31, 2025 or 2024.

10. COMMITMENTS AND CONTINGENCIES

Purchase Commitments—The Company enters contracts in the normal course of business with contract research organizations ("CROs") 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 consist of payments for services provided or expenses incurred prior to cancellation. As of December 31, 2025 and 2024 there were no amounts accrued related to termination charges.

11. NET LOSS PER COMMON SHARE

Basic and diluted loss per common share were calculated as follows:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands except share and per share amounts)	**2025**	**2024**
Net loss	$ (8,978)	$ (57,775)
Weighted-average number of common shares outstanding, basic and diluted	5,629,370	5,443,332
Net loss per common share, basic and diluted	$ (1.59)	$ (10.61)

Basic net loss per share of common stock is based on the weighted-average number of shares of common stock outstanding during the period. Pre-funded warrants to purchase 416,673 shares of common stock that were issued in connection with the November 2022 follow-on offering were included in the weighted-average number of common shares outstanding for the years ended December 31, 2025 and 2024, respectively. The weighted-average number of common shares outstanding diluted for the years ended December 31, 2025 and 2024 both exclude approximately 0.7 million stock options and nonvested restricted stock awards and units, which were not dilutive.

12. SEGMENTS

The Company defines its segments on the basis of the way in which internally reported financial information is regularly reviewed by the CODM to analyze financial performance, make decisions, and allocate resources. The Company's CODM consists of its Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. The Company manages its operations as a single operating and reportable segment and the measure of segment profit or loss is net loss. The CODM uses net loss in the budget and forecasting process and considers budget-to-actual variances on a quarterly basis when making decisions about the allocation of operating and capital resources.

The following table summarizes the information about reported segment revenues and significant segment expenses presented on the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands)	**2025**	**2024**
Revenue	$ 858	$ 636
Less:		
Research and development:		
RLYB212	6,291	21,287
RLYB116	3,786	4,841
Other program candidates	(29)	1,901
Personnel (including share-based compensation)	8,798	12,488
Other	751	990
General and administrative, excluding personnel	6,078	6,654
General and administrative, personnel (including share-based compensation)	8,247	12,971
Other segment items*	(24,086)	(2,721)
Segment net loss	$ (8,978)	$ (57,775)

*Other segment items includes total other income, net and gain and loss on investment in joint venture.

13. RESTRUCTURING

On May 2, 2025, the Company approved a workforce reduction to focus resources on the Company's lead program, RLYB116 and its preclinical development programs.

As part of this effort, the Company eliminated approximately 40% of its positions. As a result of these actions, the Company incurred charges of approximately $1.7 million of which $1.2 million was included in research and development expenses and $0.5 million was included in general and administrative expenses, with such amounts reflected in the consolidated statements of operations and comprehensive loss. The charges related to the workforce reduction were cash-based expenditures related primarily to severance and benefit payments. The Company recognized all such charges during the second quarter of 2025, with such amounts reflected in the consolidated statements of operations and comprehensive loss. The accrued restructuring liability is included in accrued expenses in the consolidated balance sheets as of December 31, 2025.

In February, 2024, the Company announced a prioritization of its portfolio and a workforce reduction to focus resources primarily on the continued development of RLYB212.

As part of this effort, the Company eliminated approximately 45% of its positions. As a result of these actions, the Company incurred charges of approximately $3.3 million of which $2.0 million was included in research and development expenses and $1.3 million was included in general and administrative expenses, with such amounts reflected in the consolidated statements of operations and comprehensive loss. The charges related to the workforce reduction are cash-based expenditures related primarily to severance and benefit payments. The Company recognized all such charges in the first quarter of 2024, with such amounts reflected in the consolidated statements of operations and comprehensive loss.

Substantially all restructuring payments are expected to be completed by August 2026.

The following table summarizes the restructuring accrued expense activity as of December 31, 2025:

(in thousands)	DECEMBER 31, 2025
Beginning accrued severance	$ 203
Severance incurred during the period	1,706
Severance paid and adjustments made during the period	(1,386)
Ending accrued severance	$ 523

14. SUBSEQUENT EVENTS

Share Price and Reverse Split

On February 24, 2025, the Company received a notification letter from The Nasdaq Stock Market LLC ("Nasdaq") Listing Qualifications Department notifying the Company that the closing bid price of the Company's shares of common stock was below the minimum closing bid price of $1.00 per share during the prior 30 consecutive business days (the "Notice"), as required for continued listing on the Nasdaq. Pursuant to Nasdaq's Listing Rules, the Company had until August 25, 2025 (the "Initial Compliance Date") to regain compliance with the minimum closing bid price requirement. As of the Initial Compliance Date, the Company had not regained compliance with the minimum closing bid price requirement.

On August 26, 2025, Nasdaq notified the Company that it had approved the Company's application to transfer its listing to the Nasdaq Capital Market and that the Company is eligible for an additional 180 calendar day period, or until February 23, 2026 (the "Second Compliance Date"), to regain compliance with the minimum closing bid price requirement. At the opening of business on August 29, 2025, the Company's common stock was transferred to the Nasdaq Capital Market, which operates in substantially the same manner as the Nasdaq Global Select Market, where it will continue to trade under the symbol "RLYB."

On January 26, 2026, the Company's stockholders approved a proposal to amend its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") with the Secretary of State of the State of Delaware to effect a reverse stock split of the Company's issued and outstanding common stock, par value $0.0001 at a ratio of 1-for-8. Pursuant to the Certificate of Amendment, the Reverse Stock Split became effective at 12:01 a.m., Eastern Time, on February 6, 2026 and began trading on a post-split basis under CUSIP number 75120L 209.

All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split.

On February 24, 2026, Rallybio received a letter from Nasdaq notifying the Company it had regained compliance with the Nasdaq's Listing Rules and that it complies with the requirements for continued listing.

Proposed Merger with Candid Therapeutics

On March 1, 2026, Rallybio entered into the Merger Agreement with Candid, a clinical-stage biotechnology company advancing a leading portfolio of TCE therapeutics for autoimmune diseases, and the Merger Sub. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into Candid, with Candid surviving as a wholly owned subsidiary of the Merger. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, (a) each then-outstanding share of common stock or preferred stock of Candid Share (excluding any share described in clauses (b) or (c) below and Candid Shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Rallybio Common Stock, par value $0.0001 per share, calculated in accordance with the Exchange Ratio, (b) each Candid Share issued in the Concurrent Financing will be converted into the right to receive a number of shares of Rallybio Common Stock calculated in accordance with the Concurrent Financing Exchange Ratio, (c) any Candid Shares held as treasury shares or held or owned by Rallybio, Merger Sub or any subsidiary of Rallybio or Candid immediately prior to the Effective Time will be canceled and shall cease to exist, and no consideration shall be delivered in

exchange therefor. Each then-outstanding option to purchase Candid Shares will be converted into an option to purchase Rallybio Common Stock, subject to adjustment as set forth in the Merger Agreement.

Concurrently with the execution and delivery of the Merger Agreement, certain investors entered into subscription agreements with Candid, pursuant to which such investors have agreed to purchase, immediately prior to the Merger, shares of Candid common stock representing an aggregate commitment of approximately $505.5 million in the Concurrent Financing. The shares of Candid common stock that are issued in the Concurrent Financing will be or will have the right to be, respectively, converted into shares of Rallybio Common Stock in the Merger.

Under the Exchange Ratio and Concurrent Financing Exchange Ratio formulas in the Merger Agreement, immediately upon the Closing, on a pro forma basis and based upon the number of shares of Rallybio Common Stock expected to be issued in connection with the Merger, pre-Merger equityholders of Candid (other than investors in the Concurrent Financing) are expected to own approximately 57.55% of the combined company, pre-Merger equityholders of Rallybio are expected to own approximately 3.65% of the combined company and the Investors in the Concurrent Financing are expected to own approximately 38.80% of the combined company (assuming proceeds from the Concurrent Financing of $505.5 million), in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) a valuation for Rallybio of $47.5 million (assuming Rallybio has net cash ("Rallybio Net Cash") of $37.5 million as of the closing of the Merger (the "Closing" and such date, the "Closing Date")), (ii) a fixed valuation for Candid of $750.0 million, and (iii) the relative capitalization of Rallybio and Candid. The percentage of the combined company that each party's equity holders will own following the Closing is subject to certain adjustments as described in the Merger Agreement, including the amount of the final Rallybio Net Cash at Closing.

Immediately prior to the Effective Time, Rallybio and a rights agent are expected to enter into the CVR Agreement, pursuant to which holders of record of certain Rallybio securities as of the close of business on the last business day prior to the day on which the Effective Time occurs will receive one contingent value right (each, a "CVR") for each outstanding share of Rallybio Common Stock, prefunded warrant, Rallybio restricted stock unit or In the Money Parent Option (as defined in the CVR Agreement) held as of such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to receive their pro rata share of (i) all of the net proceeds (including cash the value of stock to the extent listed on a national exchange, at the time of disposition), if any, received by Rallybio as a result of payments made to Rallybio of any upfront, milestone, royalty and other payments received under any disposition agreement related to Rallybio's Legacy Assets, and (ii) all of the cash proceeds, if any, received from Recursion under the Membership Interest Purchase Agreement, dated July 8, 2025, by and among Recursion, Exscientia Ventures I, Inc., Rallybio Corporation and Rallybio IPB, LLC. For a period of one year after the Closing Date, Rallybio will use commercially reasonable efforts to effect the disposition of the Legacy Assets. Such net proceeds will be subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred or other liabilities borne by Rallybio or its affiliates in respect of the Legacy Assets, and losses incurred by Rallybio or its affiliates due to a third-party proceeding in connection with such disposition.

Insider Trading Policy

1. Purpose. This Insider Trading Policy (this "Policy") provides guidelines with respect to transactions in the securities of Rallybio Corporation (the "Company") and the handling of confidential information about the Company and the companies with which it does business. The Company's Board of Directors (the "Board") has adopted this Policy to promote compliance with U.S. federal and state securities laws that prohibit certain persons who are aware of material nonpublic information about a company from: (i) trading in securities of that company; or (ii) providing such material nonpublic information to other persons who may trade on the basis of that information, commonly known as "tipping."

2. Persons Subject to the Policy. This Policy applies to all directors, officers and other employees of the Company and its subsidiaries. The Company may also determine that other persons should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information about the Company. Any such other persons will be notified by the General Counsel.

This Policy also applies to transactions by: (i) your family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), (ii) anyone else who lives in your household, (iii) any family members who do not live in your household but whose transactions in Company Securities (as defined below) are directed by you or are subject to your influence or control, such as parents or children who consult with you before they trade in Company Securities (as defined below), and (iv) family trusts, family partnerships and similar entities controlled by you or any person described in items (i)-(iii) (collectively "Other Covered Persons"). You are responsible for the transactions of these Other Covered Persons and therefore should make them aware of the need to confer with you before they trade in Company Securities (as defined below), and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account.

3. Transactions Subject to the Policy. This Policy applies to transactions in the Company's securities ("Company Securities"), including the Company's common stock, options to purchase common stock, restricted stock units or any other type of securities that the Company may issue, including, but not limited to, preferred stock, convertible debt and warrants.

4. Individual Responsibility. Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to refrain from engaging in transactions in Company Securities while in possession of material nonpublic information about the Company. Each individual is responsible for making sure that he or she complies with this Policy, and that any Other Covered Person whose transactions are subject to this Policy, as discussed above, also complies with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with that individual, and any action on the part of the Company, the General Counsel or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct

prohibited by this Policy or applicable securities laws, as described below in more detail under the heading "Consequences of Violations."

5. Administration of the Policy. The Company's General Counsel or such other officer as is designated by the Chief Executive Officer shall, in consultation with the Chief Executive Officer, be responsible for administration of this Policy. In the absence of the General Counsel, another employee designated by the General Counsel (or, if the General Counsel is unavailable, by the Chief Executive Officer) shall be responsible for administration of this Policy. All determinations and interpretations by the General Counsel or his or her delegate shall be final. References to General Counsel throughout this policy shall be interpreted to include such designee, if applicable, pursuant to this Section 5.

6. Statement of Policy. It is the policy of the Company that a director, officer or other employee of the Company or its subsidiaries (or any other person designated by the General Counsel or his or her delegate as subject to this Policy) who is aware of material nonpublic information relating to the Company should refrain from discussing such information with other employees of the Company except in connection with their responsibilities as employees of the Company, and may not, directly or indirectly through Other Covered Persons:

- engage in transactions in Company Securities, except as otherwise specified in this Policy under the headings "Transactions under Company Plans," "Transactions Not Involving a Purchase or Sale" and "Rule 10b5-1 Plans";
- pass such material nonpublic information on to others or recommend to anyone the purchase or sale of any securities when such persons are aware of such information;
- disclose such material nonpublic information to persons within the Company except to the extent directed by the Chief Executive Officer, Chief Operating Officer, Chief Financial Officer or General Counsel, or to anyone outside of the Company, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless any such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or
- assist anyone engaged in the above activities in contravention of this Policy.

In addition, it is the policy of the Company that a director, officer or employee of the Company or its subsidiaries (or any other person designated by the General Counsel or his or her delegate as subject to this Policy) who, in the course of working for the Company or its subsidiaries, learns of material nonpublic information about another public company or any of its subsidiaries, may not trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not excepted from this Policy. The securities laws do not provide exceptions for mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

7. Definition of Material Nonpublic Information.

7.1. Material Information. Information is considered "material" if a reasonable investor would consider that information important in making a decision to buy, hold or sell securities. Any information that could be expected to affect the Company's stock price, whether it is positive or negative, should be considered material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight.

While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

- results of clinical trials;
- significant regulatory developments, including feedback from the FDA and other regulatory agencies;
- timelines for clinical trials, and expected launches of new products or for new indications;
- manufacturing disruptions, including the gain or loss of a significant supplier;
- product or product candidate recalls, including as a result of regulatory of manufacturing issues;
- a pending or proposed merger, acquisition or tender offer;
- a pending or proposed acquisition or disposition of a significant asset;
- a pending or proposed joint venture or licensing agreement or other business development activities;
- a pending or proposed change to our collaboration relationships, including but not limited to changes to existing arrangements and new pending collaborations;
- significant related party transactions;
- offering of additional securities;
- a change in the Company's cost structure;
- major marketing changes;
- a change in management, including the hiring or departure of key employees;
- a change in auditors or notification that the auditor's reports may no longer be relied upon;
- pending or threatened significant litigation, or the resolution of such litigation;
- impending bankruptcy or the existence of severe liquidity problems;

- projections of future earnings or losses, or other financial guidance;
- changes to previously announced financial guidance, or the decision to suspend financial guidance;
- the imposition of a ban on trading in Company Securities or the securities of another company; and
- significant cybersecurity incidents.

7.2. Nonpublic Information. Generally, information that has not been disclosed to the public is considered to be nonpublic information. In order to establish that the information has been disclosed to the public, it may be necessary to demonstrate that the information has been widely disseminated. Information generally would be considered widely disseminated if it has been disclosed through the Dow Jones "broad tape," newswire services, a broadcast on widely available internet, radio or television programs, publication in a widely available newspaper, magazine or news website, or public disclosure documents filed with the Securities and Exchange Commission (the "SEC") that are available on the SEC's website. By contrast, information would generally not be considered widely disseminated if it is available only to the Company's directors or employees.

Once information is widely disseminated, it is still necessary to afford the investing public sufficient time to absorb the information. As a general rule, information should be considered nonpublic until the end of the first full trading day after the information is released. For example, if the Company announces financial results after market close on Monday or before trading begins on a Tuesday, the first time a director, officer or employee can buy or sell Company Securities is the opening of the market on Wednesday (assuming he or she is not aware of other material nonpublic information relating to the Company at that time). However, if the Company announces financial results after trading begins on that Tuesday, the first time a director, officer or employee can buy or sell Company Securities is the opening of the market on Thursday (again assuming he or she is not aware of other material nonpublic information relating to the Company at that time). Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific material nonpublic information.

8. Transactions under Company Plans. This Policy does not apply to the following transactions, except as specifically noted:

8.1. Stock Option Exercises. This Policy does not apply to the exercise of a stock option acquired pursuant to a Company equity incentive plan (provided the acquired Company Securities are held and not sold) or to a transaction in which a person has elected to have the Company withhold shares subject to an option award to satisfy tax withholding requirements. This Policy does, however, apply to any sale of shares as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of or taxes associated with an option.

8.2. Restricted Stock and Similar Awards. This Policy does not apply to the vesting of restricted stock, the settlement of restricted stock units or similar awards, or to

a transaction in which the Company withholds shares to satisfy tax withholding requirements upon the vesting of any restricted stock or the vesting or settlement of any restricted stock unit. This Policy does apply, however, to any market sale of restricted stock or other Company Securities received upon the settlement of any restricted stock unit or similar award.

8.3. Employee Stock Purchase Plan. This Policy does not apply to periodic purchases under a Company employee stock purchase plan, if such plan exists, that are made as the result of an election made at the beginning of the purchase period. This Policy would apply, however, to an initial decision to participate in the plan or a decision to increase the level of contribution in a subsequent purchase period. This Policy also applies to any sales of shares purchased under the plan.

8.4. 401(k) Plan. This Policy does not apply to purchases of Company Securities in the Company's 401(k) plans as a result of periodic contributions made pursuant to payroll deduction. This Policy does apply, however, to initial elections to participate, and increases or decreases in the level of participation, in a Company stock fund and transfers in or out of a Company stock fund (including in connection with a plan loan).

9. Transactions with the Company. Any purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this Policy.

10. Transactions Not Involving a Purchase or Sale. *Bona fide* gifts are not transactions subject to this Policy, unless the person making the gift has reason to believe that the recipient intends to sell the Company Securities while the officer, employee or director is aware of material nonpublic information, or the sale by the recipient of the Company Securities occurs during a Blackout Period (as defined herein).

11. In addition, transactions in mutual funds that are invested in Company Securities are not transactions subject to this Policy.

12. Special and Prohibited Transactions. The Company has determined that the following transactions present a heightened legal risk and the potential appearance of improper or inappropriate conduct. It is therefore the Company's policy that any person covered by this Policy may not engage in any of the following transactions:

12.1. Short-Term Trading. Short-term trading of Company Securities may be distracting to the person trading and may unduly focus the person on the Company's short-term performance instead of the Company's long-term business objectives. For these reasons, any director or executive officer of the Company who purchases Company Securities may not sell any Company Securities of the same class during the six months following the purchase (or vice versa). In accordance with Section 16(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), any profits received from prohibited short-term trades must be disgorged to the Company.

12.2. Short Sales. Short sales of Company Securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value and therefore might signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Exchange Act prohibits executive officers and directors from engaging in short sales.

Short sales arising from certain types of hedging transactions are also governed by the paragraph below captioned "Hedging Transactions."

12.3. Publicly Traded Options. Given the relatively short term of publicly traded options, transactions in options may create the appearance that a director, officer or employee is trading based on material nonpublic information and focus such person's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, are prohibited by this Policy.

12.4. Hedging Transactions. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a director, officer or employee to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer or employee may no longer have the same objectives as the Company's other shareholders. Therefore, directors, officers and employees are prohibited from engaging in any such transactions.

12.5. Margin Accounts and Pledged Securities. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company Securities, directors, officers and other employees are prohibited from holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan.

12.6. Standing and Limit Orders. Standing and limit orders (except standing and limit orders under Rule 10b5-1 Plans, as described below) create heightened risks for insider trading violations, similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer or other employee is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on Company Securities other than pursuant to Rule 10b5-1 Plans. If a person subject to this Policy determines that they must use a standing order or limit order, that person must contact the General Counsel for clearance to place the order.

13. Rule 10b5-1 Plans. Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities that meets certain conditions specified in the rule (a "Rule 10b5-1 Plan"). If the plan meets the requirements of Rule 10b5-1, Company Securities may be purchased or sold without regard to certain insider trading restrictions. A 10b5-1 Plan cannot be adopted during a Blackout Period. The first trade made pursuant to a 10b5-1 Plan must be (a) for directors and officers, the date that is the later of (i) 90 days after the date of adoption of the plan, and (ii) 2 business days following the disclosure in certain periodic reports of the Company's financial results for the fiscal quarter in which the plan was adopted (not to exceed 120 days following the date of adoption of the plan), and (b) for all other employees, at least 30 days after the date of adoption of the plan. To comply with this Policy, a Rule 10b5-1 Plan must be approved by the General Counsel and meet the requirements of Rule 10b5-1. In addition, a Rule 10b5-1 Plan may not be amended,

suspended or terminated by the director, officer or employee without the prior approval of the General Counsel. A Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

Rule 10b5-1 Plans will be considered by the General Counsel on a case-by-case basis. Any Rule 10b5-1 Plan must be submitted to the General Counsel for approval at least five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

14. Trading Window and Pre-Clearance Procedures. To help prevent inadvertent violations of the federal securities laws and to avoid even the appearance of trading on the basis of inside information, the following trading blackout and pre-clearance procedures are also applicable to each person subject to this Policy. These procedures generally prohibit trading in Company Securities, except during the trading windows specified below, and may require pre-clearance of transactions in Company Securities with the General Counsel as notified by the General Counsel from time to time.

15. In addition, from time to time, the Company may be involved in activities—such as proposed acquisitions—that are material. The General Counsel shall notify all persons subject to an event-specific trading restriction when one is implemented, and those individuals shall not be permitted to trade in Company Securities during such trading restriction. The existence of an event-specific trading restriction may not be widely announced and should not be communicated to anyone. Even if individuals are not notified of an event-specific trading restriction, they should not trade in Company Securities if they are aware of material nonpublic information.

15.1. Pre-Clearance Procedures. If notified in writing by the General Counsel or the General Counsel's designee, directors, officers and other employees of the Company, as well as their family members and other related persons and entities specified in the "Persons Subject to the Policy" section of this Policy, may not engage in any transaction in Company Securities at any time, even if not subject to a Blackout Period (as defined below), without first obtaining pre-clearance of the transaction from the General Counsel. A request for pre-clearance should be submitted to the General Counsel at least two trading days in advance of the proposed transaction. The General Counsel is under no obligation to approve a transaction submitted for pre-clearance, and may determine not to permit the transaction. If a person seeks pre-clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities, and should not inform any other person of the restriction.

15.2. When a request for pre-clearance is made, the requestor should carefully consider whether he or she may be aware of any material nonpublic information about the Company, and should describe fully those circumstances to the General Counsel. The requestor should also indicate whether he or she has effected any "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5, if applicable. The requestor should also be prepared to comply with SEC Rule 144 and file a Form 144, if necessary, at the time of any sale. After receiving clearance to engage in a trade from the General Counsel, the

requestor must complete the proposed trade within two trading days or make a new trading request.

15.3. Quarterly Trading Restrictions. Directors, officers and other employees of the Company, as well as their family members and other related persons and entities specified in the "Persons Subject to the Policy" section of this Policy, may not engage in any transaction in Company Securities (other than as specified below under the heading "Exceptions") during a blackout period beginning on February 10, April 10, July 10, and October 10 of each calendar year and ending after the first full trading day following the public release of the Company's earnings results for the previous quarter (the "Blackout Period"). For example, if the Company announces financial earnings before trading begins on a Tuesday, the Blackout Period will end with the opening of The Nasdaq Global Market on that Wednesday. However, if the Company announces earnings after trading begins on that Tuesday, the Blackout Period will end with the opening of The Nasdaq Global Market on that Thursday.

15.4. Event-Specific Trading Restrictions. From time to time, an event may occur that is material to the Company and is known by all or only a few directors, officers and/or employees. So long as the event remains material and nonpublic, such persons as designated by the General Counsel may not trade Company Securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the General Counsel, designated persons should refrain from trading in Company Securities prior to the commencement of the Blackout Period. In that situation, the General Counsel may notify these persons that they should not trade in the Company's Securities, without disclosing the reason for the restriction. The existence of an event-specific trading restriction period or extension of a Blackout Period may not be announced to the Company as a whole, and should not be communicated to any other person. Even if the General Counsel has not designated you as a person who should not trade due to an event-specific restriction, you should not trade while aware of material nonpublic information.

15.5. Exceptions. The quarterly trading restrictions and event-specific trading restrictions described above do not apply to those transactions to which this Policy does not apply, as described therein under the headings "Transactions Under Company Plans," "Transactions Not Involving a Purchase or Sale" and "Transactions with the Company." Further, the requirement for pre-clearance, the quarterly trading restrictions and event-specific trading restrictions do not apply to transactions conducted pursuant to approved Rule 10b5-1 plans, described in this Policy under the heading "Rule 10b5-1 Plans."

16. Post-Termination Transactions. This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material.

17. Consequences of Violations. The purchase or sale of securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then trade in the Company Securities, is prohibited by U.S. federal and state laws. Insider trading violations are pursued vigorously by the SEC, U.S. Attorneys and state enforcement authorities, as well as foreign regulatory authorities. Punishment for insider trading violations is severe, and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other

"controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, an individual's failure to comply with this Policy may subject the individual to Company-imposed sanctions, including dismissal for cause, whether or not the employee's failure to comply results in a violation of law. In addition to the formal sanctions summarized above, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

18. Company Assistance. Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the General Counsel.

19. Certification. All persons subject to this Policy must certify their understanding of, and intent to comply with, this Policy (in such written or electronic format as may be specified by the Company).

20.

21. Updated May 17, 2023

CERTIFICATION

I certify that:

1. I have read and understand the Company's Insider Trading Policy (the "Policy"). I understand that the General Counsel is available to answer any questions I have regarding the Policy.

2. Since the effective date of this policy, or such shorter period of time that I have been an employee, officer or director of the Company, or otherwise subject to the Policy, I have complied with the Policy.

3. I will continue to comply with the Policy for as long as I am subject to the Policy.

Print name: __

Signature: __

Date: __

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-271748, and 333-279317 on Form S-3 and Registration Statement Nos. 333-258383, 333-265443, 333-271805, 333-277880, and 333-287143 on Form S-8 of our report dated March 16, 2026, relating to the financial statements of Rallybio Corporation appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP
Hartford, Connecticut
March 16, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Uden, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rallybio Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2026

By: /s/ Stephen Uden

Stephen Uden M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan I. Lieber, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rallybio Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2026

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Rallybio Corporation (the "Company") on Form 10-K for the period ending December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 16, 2026

By: /s/ Stephen Uden

Stephen Uden, M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Rallybio Corporation (the "Company") on Form 10-K for the period ending December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 16, 2026

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

RALLYBIO CORPORATION
POLICY FOR RECOUPMENT OF INCENTIVE COMPENSATION

1. Introduction

In accordance with Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the regulations thereunder, the Board of Directors (the "Board") of Rallybio Corporation (the "Company") has adopted a policy (the "Policy") providing for the Company's recoupment of certain incentive-based compensation received by Covered Executives (as defined below) in the event that the Company is required to prepare an accounting restatement due to its material noncompliance with any financial reporting requirement under the securities laws. This Policy is designed to comply with, and shall be construed and interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated under the Exchange Act and Listing Rule 5608 of the corporate governance rules of The Nasdaq Stock Market.

2. Administration

Administration and enforcement of this Policy is delegated to the Compensation Committee of the Board (as constituted from time to time, and including any successor committee, the "Committee"). The Committee shall make all determinations under this Policy in its sole discretion. Determinations of the Committee under this Policy need not be uniform with respect to any or all Covered Executives and will be final and binding.

3. Effective Date

This Policy shall be effective as of October 2, 2023 (the "Effective Date") and shall apply only to Covered Compensation (as defined below) that is received by Covered Executives on or after the Effective Date.

4. Covered Executives

This Policy covers each current or former officer of the Company subject to Section 16 of the Exchange Act (each, a "Covered Executive").

5. Covered Compensation

This Policy applies to any cash-based and equity-based incentive compensation, bonuses, and awards that are received by a Covered Executive and that were based, wholly or in part, upon the attainment of any financial reporting measure ("Covered Compensation"). For the avoidance of doubt, none of the following shall be deemed to be Covered Compensation: base salary, a bonus that is paid solely at the discretion of the Committee or Board and not paid from a bonus pool determined by satisfying a financial reporting measure performance goal, and cash or equity-based awards that are earned solely upon satisfaction of one or more subjective or strategic standards. This Policy shall apply to any Covered Compensation received by an employee who served as a Covered Executive at any time during the performance period for that Covered Compensation.

6. Financial Restatements; Recoupment

In the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (such an accounting restatement, a "Restatement"), the Committee shall review the Covered Compensation received by a Covered Executive during the three-year period preceding the Required Financial Restatement Date as well as any transition period that results from a change in the Company's fiscal year within or immediately following those three completed fiscal years. Regardless of whether the Company filed the restated financial statements, the Committee shall, to the full extent permitted by governing law, seek recoupment of any Covered Compensation, whether in the form of cash or equity, received by a Covered Executive (computed without regard to any taxes paid), if and to the extent:

a. the amount of the Covered Compensation was calculated based upon the achievement of certain financial results that were subsequently the subject of a Restatement; and

b. the amount of the Covered Compensation that would have been received by the Covered Executive had the financial results been properly reported would have been lower than the amount actually awarded (any such amount, "Erroneously-Awarded Compensation").

To the extent Covered Compensation was based on the achievement of a financial reporting measure, but the amount of such Covered Compensation was not awarded or paid on a formulaic basis, the Committee shall determine the amount, if any, of such Covered Compensation that is deemed to be Erroneously-Awarded Compensation.

For purposes of this Policy, the "Required Financial Restatement Date" is the earlier to occur of:

a. the date the Board, a committee of the Board, or any officer or officers authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or

b. the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement.

For the avoidance of doubt, a Covered Executive will be deemed to have received Covered Compensation in the Company's fiscal period during which the financial reporting measure specified in the award is attained, even if the Covered Executive remains subject to additional payment conditions with respect to such award.

7. Method of Recoupment

The Committee will determine, in its sole discretion, the method for recouping Erroneously-Awarded Compensation, which may include, without limitation:

a. requiring reimbursement of cash incentive compensation previously paid;

b. cancelling or rescinding some or all outstanding vested or unvested equity (and/or equity-based) awards;

c. adjusting or withholding from unpaid compensation or other set-off to the extent permitted by applicable law; and/or

d. reducing or eliminating future salary increases, cash-based or equity-based incentive compensation, bonuses, awards or severance.

8. Impracticability Exceptions

The Committee shall not seek recoupment of any Erroneously-Awarded Compensation to the extent it determines that:

a. the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of Erroneously-Awarded Compensation to be recovered;

b. recovery would violate home country law where that law was adopted prior to November 28, 2022; and/or

c. recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to Company employees, to fail to meet the requirements of Sections 401(a)(13) and 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

9. No Indemnification

For the avoidance of doubt, the Company shall not indemnify any Covered Executive against the loss of any Erroneously-Awarded Compensation or any Covered Compensation that is recouped pursuant to the terms of this Policy, or any claims relating to the Company's enforcement of its rights under this Policy.

10. Severability

If any provision of this Policy or the application of any such provision to any Covered Executive shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

11. Amendments

The Committee may amend, modify or terminate this Policy in whole or in part at any time and may adopt such rules and procedures that it deems necessary or appropriate to implement this Policy or to comply with applicable laws and regulations.

12. No Impairment of Other Remedies

The remedies under this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company may have, the Company's ability to enforce, without duplication, the recoupment provisions set forth in any separate Company policy or in any Company plan, program or agreement (each, a "Separate Recoupment Policy" and collectively, the "Separate Recoupment Policies"), or any actions that may be imposed by law enforcement agencies, regulators or other authorities. Notwithstanding the foregoing, in the event that there is a conflict between the application of this Policy to a Covered Executive in the event of a Restatement and any additional recoupment provisions set forth in a Separate Recoupment Policy to which a Covered Executive is subject, the provisions of this Policy shall control. The Company may also adopt additional Separate Recoupment Policies in the future or amend existing requirements as required by law or regulation.

September 13, 2023