UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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, Suite 1020 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 Global Select Market

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of August 1, 2022, the registrant had 32,131,970 shares of common stock, $0.0001 par value per share, outstanding.

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials for RLYB211, RLYB212, RLYB116 and RLYB331, and the natural history study for our FNAIT prevention program, and related preparatory work, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates, including RLYB212, RLYB116, RLYB114, and RLYB331;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including PNH and gMG;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- the size and growth potential of the markets for RLYB212, RLYB116, RLYB114, RLYB331 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- our ability to expand our pipeline through collaborations, partnerships and other transactions with third parties;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds from our initial public offering;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the time during which we will be an emerging growth company under the 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report on Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. 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 and/or in other countries. This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q. These risks include the following:

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

incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;

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

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

RALLYBIO CORPORATION

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share amounts)	JUNE 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 60,753	$ 175,334
Marketable securities	86,615	—
Prepaid expenses and other assets	6,931	5,535
Total current assets	154,299	180,869
Property and equipment, net	468	511
Operating lease right-of-use assets	613	—
Investment in joint venture	227	805
Total assets	$ 155,607	$ 182,185
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 633	$ 603
Accrued expenses	6,495	5,948
Operating lease liabilities	150	—
Total current liabilities	7,278	6,551
Accrued expenses, noncurrent	—	32
Operating lease liabilities, noncurrent	478	—
Total liabilities	7,756	6,583
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively; and 32,130,970 and 32,129,970 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	3	3
Preferred stock, $0.0001 par value per share; 50,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively; no shares issued or outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	274,327	269,626
Accumulated other comprehensive loss	(371)	—
Accumulated deficit	(126,108)	(94,027)
Total stockholders' equity	147,851	175,602
Total liabilities and stockholders' equity	$ 155,607	$ 182,185

See accompanying notes of the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share amounts)	FOR THE THREE MONTHS ENDED JUNE 30, 2022	FOR THE THREE MONTHS ENDED JUNE 30, 2021	FOR THE SIX MONTHS ENDED JUNE 30, 2022	FOR THE SIX MONTHS ENDED JUNE 30, 2021
Operating expenses:				
Research and development	$ 10,138	$ 6,818	$ 17,786	$ 15,855
General and administrative	7,477	3,712	14,147	7,499
Total operating expenses	17,615	10,530	31,933	23,354
Loss from operations	(17,615)	(10,530)	(31,933)	(23,354)
Other income (expenses):				
Interest income	270	13	367	30
Interest expense	—	—	—	(10)
Other income (expense)	100	(142)	213	(118)
Total other income (expense), net	370	(129)	580	(98)
Loss from continuing operations	(17,245)	(10,659)	(31,353)	(23,452)
Loss on investment in joint venture	338	468	728	950
Net loss	$ (17,583)	$ (11,127)	$ (32,081)	$ (24,402)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.49)	$ (1.05)	$ (1.09)
Weighted average common shares outstanding, basic and diluted	30,588,931	22,559,706	30,453,913	22,309,203
Other comprehensive loss:				
Net unrealized loss on marketable securities	249	—	371	—
Other comprehensive loss	(249)	—	(371)	—
Comprehensive loss	$ (17,832)	$ (11,127)	$ (32,452)	$ (24,402)

See accompanying notes of the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

For the Three Months Ended June 30, 2022 and 2021	COMMON		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	STOCKHOLDERS'
(in thousands, except share amounts)	**SHARES**	**AMOUNT**	**CAPITAL**	**DEFICIT**	**LOSS**	**EQUITY**
March 31, 2021	24,990,263	$ 2	$ 183,537	$ (60,289)	$ —	$ 123,250
Issuance of restricted common stock	9,707	—	—	—	—	—
Share-based compensation expense	—	—	539	—	—	539
Net loss	—	—	—	(11,127)	—	(11,127)
Other comprehensive loss	—	—	—	—	—	—
Balance, June 30, 2021	24,999,970	$ 2	$ 184,076	$ (71,416)	$ —	$ 112,662
March 31, 2022	32,130,970	$ 3	$ 271,680	$ (108,525)	$ (122)	$ 163,036
Share-based compensation expense	—	—	2,647	—	—	2,647
Net loss	—	—	—	(17,583)	—	(17,583)
Other comprehensive loss	—	—	—	—	(249)	(249)
Balance, June 30, 2022	32,130,970	$ 3	$ 274,327	$ (126,108)	$ (371)	$ 147,851

For the Six Months Ended June 30, 2022 and 2021	COMMON		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	STOCKHOLDERS'
(in thousands, except share amounts)	**SHARES**	**AMOUNT**	**CAPITAL**	**DEFICIT**	**LOSS**	**EQUITY**
December 31, 2020	23,410,348	$ 2	$ 183,015	$ (47,014)	$ —	$ 136,003
Issuance of restricted common stock	1,589,622	—	—	—	—	—
Share-based compensation expense	—	—	1,061	—	—	1,061
Net loss	—	—	—	(24,402)	—	(24,402)
Other comprehensive loss	—	—	—	—	—	—
Balance, June 30, 2021	24,999,970	$ 2	$ 184,076	$ (71,416)	$ —	$ 112,662
December 31, 2021	32,129,970	$ 3	$ 269,626	$ (94,027)	$ —	$ 175,602
Share-based compensation expense	—	—	4,701	—	—	4,701
Issuance of common stock under the stock award plan	1,000	—	—	—	—	—
Net loss	—	—	—	(32,081)	—	(32,081)
Other comprehensive loss	—	—	—	—	(371)	(371)
Balance, June 30, 2022	32,130,970	$ 3	$ 274,327	$ (126,108)	$ (371)	$ 147,851

See accompanying notes of the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)	SIX MONTHS ENDED JUNE 30, 2022	2021
Cash Flows used in Operating Activities:		
Net loss	$ (32,081)	$ (24,402)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	86	48
Net accretion of discounts/premiums on debt securities	109	—
Stock-based compensation	4,701	1,061
Loss on investment in joint venture	728	950
Changes in operating assets and liabilities:		
Prepaid expenses, right-of-use assets and other assets	(1,308)	(2,249)
Accounts payable	23	787
Accrued expenses and operating lease liability	457	(970)
Net cash used in operating activities	$ (27,285)	$ (24,775)
Cash Flows used in Investing Activities:		
Purchases of marketable securities	(109,096)	—
Proceeds from maturities of marketable securities	22,000	—
Purchase of property and equipment	(50)	(66)
Investment in joint venture	(150)	(2,000)
Net cash used in investing activities	$ (87,296)	$ (2,066)
Cash Flows from Financing Activities:		
Payments of offering costs	—	(663)
Net cash used by financing activities	$ —	$ (663)
Net decrease in cash and cash equivalents	(114,581)	(27,504)
Cash and cash equivalents—beginning of period	175,334	140,233
Cash and cash equivalents—end of period	$ 60,753	$ 112,729
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Offering costs in accounts payable and accrued expenses	$ —	$ 1,762
Property and equipment in accounts payable and accrued expenses	$ 6	$ 15

See accompanying notes of the condensed consolidated financial statements

1. BUSINESS AND LIQUIDITY

Rallybio Corporation and subsidiaries (the "Company", "we", "our", or "us") is a clinical-stage biotechnology company built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing, and delivering therapies to meaningfully improve the lives of patients suffering from severe and rare diseases.

In August 2021, the Company completed its initial public offering ("IPO"), pursuant to which it issued and sold 7,130,000 shares of the Company's common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. The gross proceeds from the IPO, including the exercise of the underwriter's option to purchase additional shares were $92.7 million and the net proceeds were approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs.

The Company had cash, cash equivalents and marketable securities of $147.4 million at June 30, 2022. 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 the condensed consolidated financial statements are issued. However, we do not anticipate that the current cash, cash equivalents and marketable securities as of June 30, 2022 will be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates, if approved. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

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

Unaudited Financial Information — The unaudited condensed consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). 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 interim 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. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

The accompanying unaudited condensed consolidated financial statements include the accounts of Rallybio Corporation and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

These accompanying unaudited condensed consolidated financial statements and notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2021 (our "Annual Report") which includes a description of reorganization and liquidation of Rallybio Holdings, LLC ("Rallybio Holdings") prior to our IPO that resulted in a change in reporting entity as described in Accounting Standards Codification ("ASC") 250. In accordance with the guidance applicable to these circumstances, the equity structure has been adjusted in all comparative periods to reflect the number of shares of the Company's common stock issued to Rallybio Holdings unitholders in connection with the liquidation. As such, historical Rallybio Holdings convertible redeemable preferred units, common units, and incentive units have been retroactively adjusted in these condensed consolidated financial statements to shares and earnings per share in accordance with the ratio of common shares received by each membership unit class during the liquidation.

Our significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in our Annual Report. Updates to our accounting policies, including impacts from the adoption of new accounting standards are discussed below.

Marketable Securities — We invest our excess cash balances in highly rated 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 income (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 condensed 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 income (loss).

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-02 "Leases" that requires lessees to recognize leases on-balance sheet and to make certain disclosures associated with their leasing arrangements. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize an ROU asset and lease liability on the condensed consolidated balance sheets for all leases with a term longer than twelve months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the condensed consolidated statements of operations and comprehensive loss. The Company adopted ASU 2016-02 Leases on January 1, 2022 using the modified retrospective approach and elected to apply the transition method that allows companies to continue applying guidance under the lease standard in effect at that time in the comparative periods condensed consolidated financial statements and recognize a cumulative-effect adjustment to the condensed consolidated balance sheets on the date of adoption. The Company elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and initial direct costs. At adoption we recognized approximately $0.7 million of ROU assets and corresponding lease liabilities. See Note 6.

In June 2016, the FASB issued ASC 2016-13 "Financial Instruments - Credit Losses", a new standard intended to improve reporting requirements specific to loans, receivables and other financial instruments. The new standard requires that credit losses on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. We adopted the new standard on January 1, 2022 and have completed our assessment of the standard based on the composition of our portfolio of financial instruments. Our significant financial assets that are within the scope of the new standard consist of available for sale debt securities. There was no impact to our condensed consolidated statements of operations and comprehensive loss or condensed consolidated balance sheets upon adoption. See Note 4 for discussion of unrealized losses on our available for sale marketable securities.

3. 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.

In May 2022, we obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, a preclinical potentially first-in-class antibody that 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 myelodysplastic syndromes. 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 milestone payments and up to an aggregate of $150.0 million in commercial milestone payments 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 accompanying condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022.

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 June 30, 2022 was as follows:

	JUNE 30, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 86,986	$ —	$ (371)	$ 86,615
Money market funds	13,773	—	—	13,773
	$ 100,759	$ —	$ (371)	$ 100,388

The fair values of marketable securities by classification in the condensed consolidated balance sheets was as follows:

(in thousands)	JUNE 30, 2022
Cash and cash equivalents	$ 13,773
Marketable securities	86,615
	$ 100,388

The fair values of available-for-sale debt securities as of June 30, 2022 , by contractual maturity, are summarized as follows:

(in thousands)	JUNE 30, 2022
Due in one year or less	$ 100,388
Due after one year through two years	—
	$ 100,388

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of June 30, 2022 was $86.6 million. We did not have any investments in a continuous unrealized loss position for more than twelve months as of June 30, 2022. As of June 30, 2022, we believe that the cost basis of our available-for-sale debt securities is recoverable. No allowance for credit losses was recorded as of June 30, 2022.

5. 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). 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. The Company's principal financial instruments comprise of cash, cash equivalents and marketable securities. 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).

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.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of June 30, 2022 was as follows:

	JUNE 30, 2022		
(in thousands)	Level 1	Level 2	Level 3
Financial assets:			
Money market fund	$ 13,773	$ —	$ —
U.S. treasury securities	86,615	—	—
Total financial assets	$ 100,388	$ —	$ —

There were no securities transferred between Level 1, 2 and 3 during the six months ended June 30, 2022.

For the year ended December 31, 2021, the Company held money market funds that were classified as cash and cash equivalents on the Company's condensed consolidated balance sheets of $4.0 million. These money market funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

6. 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 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. The weighted average discount rate utilized on our operating lease liabilities as of June 30, 2022 was 4.00%.

We have operating leases for approximately nine thousand square feet of corporate office space. 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 condensed 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. The weighted average remaining lease term is 3.0 years.

Operating leases are included in ROU operating assets, other current liabilities, and noncurrent operating lease liabilities in our condensed consolidated balance sheets as of June 30, 2022.

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

(in thousands)	JUNE 30, 2022
Assets:	
Operating lease right-of-use assets	$ 613
Liabilities:	
Operating lease liabilities	$ 150
Operating lease liabilities, noncurrent	478
Total operating lease liabilities	$ 628

Future minimum lease payments from June 30, 2022 until the expiration of the operating lease are as follows:

(in thousands)	
2022	$ 86
2023	200
2024	230
2025	156
Thereafter	—
Total lease payments	672
Less: imputed discount rate	(44)
Carrying value of operating lease liabilities	$ 628

The Company incurred $51 thousand and $28 thousand in operating lease rent expense for the three months ended June 30, 2022 and 2021, respectively and $102 thousand and $54 thousand for the six months ended June 30, 2022 and 2021, respectively. Lease payments made were $43 thousand and $20 thousand for the three months ended June 30, 2022 and 2021, respectively and $87 thousand and $39 thousand for the six months ended June 30, 2022 and 2021, respectively, with such amounts reflected in the condensed consolidated statements of cash flows in operating activities.

As the result of adopting ASU 2016-02 Leases using the modified retrospective transition method, we did not restate periods prior to the adoption date of January 1, 2022. These periods continue to be presented in accordance with ASC 840. As of December 31, 2021, the future undiscounted minimum lease payments on our operating leases was as follows:

YEAR ENDING DECEMBER 31, (in thousands)	
2022	$ 170
2023	195
2024	230
2025	176
Thereafter	—
	$ 771

7. ACCRUED EXPENSES

Accrued expenses consisted of the following as of June 30, 2022 and December 31, 2021:

(in thousands)	JUNE 30, 2022	DECEMBER 31, 2021
Research and development	$ 2,847	$ 1,937
Employee expenses	2,680	2,955
Professional fees	445	539
Other	523	517
	$ 6,495	$ 5,948

8. STOCKHOLDERS' EQUITY

In August 2021, the Company completed its IPO, pursuant to which it issued and sold 7,130,000 shares of the Company’s common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $13.00 per share. The gross proceeds from the IPO, including the exercise of the underwriter's option to purchase additional shares were $92.7 million and the net proceeds were approximately $83.0 million, after deducting underwriting discounts and commissions and other offering

costs.

A reorganization and liquidation of Rallybio Holdings, LLC was completed prior to the Company's IPO, which resulted in a change in reporting entity to Rallybio Corporation. In accordance with the applicable accounting guidance related to changes in reporting entities, the financial statements for all periods presented have been retrospectively adjusted giving effect to the reorganization and liquidation as applicable to all periods presented.

Preferred Stock—The Company had 50,000,000 shares of preferred stock authorized as of June 30, 2022 and December 31, 2021, respectively, of which no shares were outstanding as of June 30, 2022 and December 31, 2021.

Common Stock—The Company had 200,000,000 shares of common stock authorized as of June 30, 2022 and December 31, 2021, respectively, of which 32,130,970 and 32,129,970 shares were issued and outstanding as of June 30, 2022 and December 31, 2021.

Share-based Compensation—

2021 Equity Incentive Plan
In 2021, the board of directors adopted the Rallybio Corporation 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan reserves 5,440,344 for 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 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. On January 1, 2022, the 2021 Plan share pool was automatically increased by 1,606,549 shares. As of June 30, 2022, the total number of shares of common stock that were issuable under the 2021 Plan was 4,659,970 shares, of which 1,826,218 shares remained available for future issuance.

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 reserves 291,324 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 and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. In 2022 the 2021 ESPP share pool was automatically increased by 321,309 shares. During the six months ended June 30, 2022, there was no activity under the 2021 ESPP.

Share-based compensation for stock options, restricted stock awards and restricted stock units is classified in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021 and was as follows:

	FOR THE THREE MONTHS ENDED JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
(in thousands)	2022	2021	2022	2021
Research and development	$ 911	$ 193	$ 1,636	$ 354
General and administrative	1,736	346	3,065	707
	$ 2,647	$ 539	$ 4,701	$ 1,061

The following table summarizes stock option activity for the six months ended June 30, 2022:

Stock Options	Number of Option Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	1,357,784	$ 12.72	9.7	$ —
Granted	1,392,995	$ 13.70		
Exercised	—	$ —		
Forfeited	(4,027)	$ 10.38		
Outstanding at June 30, 2022	2,746,752	$ 13.22	9.4	$ —
Options exercisable at June 30, 2022	249,700	$ 13.44	8.8	$ —

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. Options outstanding and exercisable with an exercise price above the closing price as of June 30, 2022 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 six months ended June 30, 2022 was $10.17 per share. There were no stock options granted during the six months ended June 30, 2021. Options vested during the six months ended June 30, 2022 with an exercise price above the closing price as of June 30, 2022 are considered to have no intrinsic value. As of June 30, 2022, there was unrecognized share-based compensation expense related to unvested stock options of $22.1 million, which the Company expects to recognize over a weighted-average period of approximately 3.3 years.

The fair value of the stock options granted during the six months ended June 30, 2022 was determined using the Black-Scholes option pricing model with the following assumptions:

	FOR THE SIX MONTHS ENDED JUNE 30,
	2022
Expected volatility	89.3% - 90.8%
Expected term (years)	5.50 - 6.08
Risk free interest rate	1.42% - 2.94%
Expected dividend yield	—
Exercise price	$7.68 - $15.04

A summary of the status of the Company's nonvested restricted common stock awards at June 30, 2022 and changes during the six months ended June 30, 2022 was as follows:

Restricted Stock Awards	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested restricted stock awards at December 31, 2021	2,272,707	$ 3.22
Shares granted	—	$ —
Shares vested	(810,881)	$ 2.99
Outstanding nonvested restricted stock awards at June 30, 2022	1,461,826	$ 3.35

As of June 30, 2022, there was unrecognized share-based compensation expense related to unvested restricted stock awards of $4.7 million, which the Company expects to recognize over a weighted-average period of approximately 2.6 years.

A summary of the status of the Company's nonvested restricted common stock units at June 30, 2022 and changes during the six months ended June 30, 2022 was as follows:

Restricted Stock Units	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested restricted stock units at December 31, 2021	2,000	$ 10.76
Shares granted	86,000	$ 14.38
Shares vested	(1,000)	$ 10.76
Outstanding nonvested restricted stock units at June 30, 2022	87,000	$ 14.34

As of June 30, 2022, there was unrecognized share-based compensation expense related to unvested restricted stock units of $1.1 million, which the Company expects to recognize over a weighted-average period of approximately 2.7 years.

9. INVESTMENT IN JOINT VENTURE

The Company, through one of its wholly-owned subsidiaries, has a 50% interest of the joint venture entity, RE Ventures I, LLC, a limited liability company ("REV-I"). For the three months ended June 30, 2022 and 2021, the Company funded $0.2 million and $1.5 million, respectively, associated with the Company's commitment and its share of REV-I development. For the six months ended June 30, 2022 and 2021 the Company funded $0.2 million and $2.0 million, respectively, associated with the Company's commitment and its share of REV-I development. The Company did not provide any additional financial support outside of capital contributions to REV-I during the three and six months ended June 30, 2022 and 2021. While the Company held a 50% interest in the joint venture as of June 30, 2022, based on management's analysis, the Company is not the primary beneficiary of REV-1 and accordingly, the entity is not consolidated in the Company's financial statements.

For the three months ended June 30, 2022 and 2021, the Company recorded its allocable share of REV-I's losses, which totaled $0.3 million and $0.5 million, respectively, and $0.7 million and $1.0 million for the six months ended June 30, 2022 and 2021, respectively, as a loss on investment in joint venture within the condensed 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 as of June 30, 2022 and December 31, 2021 was $0.2 million and $0.8 million, respectively, which was recorded in investment in joint venture in the accompanying condensed consolidated balance sheets.

10. COMMITMENTS AND CONTINGENCIES

Purchase Commitments—The Company enters contracts in the normal course of business with contract research organizations and other third-party vendors for clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consist of payments for services provided or expenses incurred prior to cancellation. As of June 30, 2022 and December 31, 2021 there were no amounts accrued related to termination charges.

11. NET LOSS PER COMMON SHARE

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

	FOR THE THREE MONTHS ENDED JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
(in thousands except share and per share amounts)	**2022**	**2021**	**2022**	**2021**
Net loss	$ (17,583)	$ (11,127)	$ (32,081)	$ (24,402)
Weighted average number of common shares outstanding, basic and diluted	30,588,931	22,559,706	30,453,913	22,309,203
Net loss per common share, basic and diluted	$ (0.57)	$ (0.49)	$ (1.05)	$ (1.09)

The weighted average number of common shares outstanding diluted for the three and six months ended June 30, 2022 excludes approximately 4.3 million stock options and unvested restricted share awards/units, which were not dilutive and not included in the computation of net loss per common share. The weighted average number of common shares outstanding diluted for the three and six months ended June 30, 2021 excludes approximately 2.4 million unvested restricted share awards/units which were not dilutive and not included in the computation of net loss per common share.

Item 2. 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 unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 II, Item 1A of this Quarterly Report on Form 10-Q, 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 built around a team of seasoned industry experts with a shared purpose and a track record of success in discovering, developing, manufacturing and delivering therapies that meaningfully improve the lives of patients suffering from severe and rare diseases. Our mission at Rallybio is aligned with our expertise, and we believe we have assembled the best people, partners and science to forge new paths to life-changing therapies. Since our launch in January 2018, we have acquired a portfolio of promising product candidates and we are focused on further expanding our portfolio with the goal of making a profound impact on the lives of even more patients. We are drawing on our decades of knowledge and experience with a determination to tackle the undone, the too difficult, the inaccessible – and change the odds for rare disease patients.

RLYB212 & RLYB211

Our most advanced program is for the prevention of fetal and neonatal alloimmune thrombocytopenia ("FNAIT"), a potentially life-threatening rare hematological disease that impacts fetuses and newborns. We are evaluating RLYB211, a polyclonal anti-HPA-1a antibody, in a Phase 1/2 clinical trial, which we believe has established proof of concept for RLYB211 and provides support for our proposed mechanism of action. Our lead product candidate is RLYB212, a monoclonal anti-HPA-1a antibody. We submitted a clinical trial application ("CTA") for RLYB212 in July 2021 and initiated a Phase 1 first-in-human trial in Germany in the fourth quarter of 2021. In January 2022, we announced that the first subjects were dosed in the Phase 1 study of RLYB212. This ongoing single-blind, placebo-controlled Phase 1 study is designed to evaluate the safety and pharmacokinetic ("PK") of single and repeat subcutaneous doses of RLYB212 in HPA-1a negative healthy subjects. In the second quarter of 2022, we initiated a Phase 1b proof-of-concept study to establish the ability of RLYB212 to rapidly eliminate transfused HPA-1a positive platelets from the circulation of HPA-1a negative healthy subjects.

In August 2022, we announced that the clinical data from our ongoing Phase 1b proof-of-concept study of subcutaneous RLYB212 shows rapid and complete elimination of transfused HPA-1a positive platelets. These data are consistent with the projected effective therapeutic target concentrations of RLYB212 required to prevent maternal alloimmunization and FNAIT. In order to further characterize the advantages associated with subcutaneous dosing, we are amending the protocol to expand the dose range of RLYB212. This amendment will provide a broader range of PK and pharmacodynamics (PD) data to inform decision-making as we seek to select dosing for a future registrational study. We expect to discuss the preliminary platelet elimination data by the end of the third quarter of 2022 as planned and to release proof-of-concept data in the first quarter of 2023.

Additionally, in the third quarter of 2021, we initiated a FNAIT natural history alloimmunization study. This prospective, non-interventional, multinational natural history study is designed to screen up to 30,000 expectant mothers presenting at Gestation Week 10 to 14 prenatal visit to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. We expect that data from this study will contribute to a control dataset for a future single-arm Phase 2/3 registration trial for RLYB212. The FNAIT natural history study will operationalize de novo the laboratory test paradigm for FNAIT risk and generate FNAIT laboratory test performance data for future regulatory discussions. Screening of expectant mothers is currently underway.

RLYB116 & RLYB114

We are also focused on developing therapies that address diseases of complement dysregulation, including paroxysmal nocturnal hemoglobinuria ("PNH"), generalized myasthenia gravis ("gMG"), and ophthalmic disorders. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5 ("C5") in development for the treatment of patients with PNH and gMG. We received approval in the fourth quarter of 2021 for a Human Research Ethics Committee ("HREC") submission to support the Phase 1 trial of RLYB116 in healthy participants and in the first quarter of 2022, we initiated the Phase 1 trial in Australia. The single-blind, placebo-controlled dose escalation study is designed to evaluate the safety, PK, and pharmacodynamics of single dose RLYB116 in healthy volunteers and remains on track, with initial data expected for the 30 mg dose in the fourth quarter of 2022. RLYB114 is a pegylated C5 inhibitor in preclinical development for the treatment of complement-mediated ophthalmic diseases.

RLYB331

In May 2022, we obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, a preclinical potentially first-in-class antibody. We believe RLYB331 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 myelodysplastic syndromes. Currently these patients are underserved by the existing standard of care. RLYB331 is a monoclonal antibody that inhibits Matriptase-2 ("MTP-2"). The inhibition of MTP-2 significantly increases levels of

hepcidin, decreases iron load and treats ineffective erythropoiesis. We are conducting IND-enabling activities for RLYB331 to support transition of the asset into clinical development.

Other Programs

Additionally, in collaboration with Exscientia Limited ("Exscientia"), we have two discovery-stage programs focused on the identification of small molecule therapeutics for patients with rare metabolic diseases. Rallybio, together with its partner Exscientia, continues to work toward the selection of a development candidate to advance into the clinic targeting ENPP1 for the treatment of patients with hypophosphatasia ("HPP"). Investigational new drug enabling studies are expected to commence in the second half of 2022.

Recent Developments

Rallybio announced in June 2022 that Jeffrey Fryer, CPA, will retire from his position as Chief Financial Officer ("CFO"). Mr. Fryer will continue to serve as Rallybio's CFO until a new CFO has been appointed and will retire from the Company following a transition period. Rallybio has initiated an external search to identify its next CFO.

In August 2022, Rallybio announced the appointment of Wendy Chung, M.D., Ph.D., to its Board of Directors.

Our Operations

Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates, preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our 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 IPO, we received proceeds of approximately $182.5 million from equity financing. In August 2021, we closed our IPO and issued and sold 7,130,000 shares of common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs paid by us.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of $147.4 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 the first quarter of 2024. This estimate and our expectation to advance the preclinical and clinical development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate. See "—Liquidity and Capital Resources."

We have incurred significant operating losses since inception, including net losses of $17.6 million and $11.1 million for the three months ended June 30, 2022 and 2021, respectively and $32.1 million and $24.4 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $126.1 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. We expect to incur significant additional operating losses in the foreseeable future as we advance our programs through preclinical and clinical development, expand our research and development activities, acquire and develop new product candidates, complete preclinical studies and clinical trials, finance our business development strategy, seek regulatory approval for the commercialization of our product candidates and commercialize our products, if approved. Our expenses will increase substantially if and as we:

- advance our Phase 1 clinical trial for RLYB212, our lead product candidate for our FNAIT prevention program;
- advance our clinical trial for RLYB116, and file an IND or a CTA for other product candidates;
- advance our natural history alloimmunization study of FNAIT and other studies to support our development program and related regulatory submissions for RLYB212;
- continue to develop and conduct clinical trials with respect to RLYB211;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- continue and expand upon our discovery and development joint venture with Exscientia;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;

- add operational, financial, and management personnel, including personnel to support our product development and planned future commercialization efforts and to support our operations as a public company;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any product candidate for which we obtain regulatory approval; and
- establish a sales, marketing and distribution infrastructure to commercialize our programs, if approved, and for any other product candidates for which we may obtain marketing approval.

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

Impact of COVID-19

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

We continue to monitor the potential impact of the COVID-19 pandemic on our business and financial statements. To date, we have not incurred impairment losses in the carrying values of our assets as a result of the COVID-19 pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our financial statements. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures.

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

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist 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 fees paid to contract manufacturer organizations ("CMOs");
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- 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;
- the costs of acquiring and developing clinical trial materials;
- expenses to acquire technologies, such as intellectual property, to be used in research and development including in-process research and development ("IPR&D") that has no alternative future use at the time of asset acquisitions;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other indirect costs 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 balances at the end of any reporting period.

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

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

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

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;

- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

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

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.

Total Other Income (Expense), Net

Total other income (expense), net, includes interest income earned on cash, cash equivalents and marketable securities, interest expense and other income and expense items.

Loss on Investment in Joint Venture

The Company recognizes its pro-rata share of losses in the joint venture with Exscientia on its condensed 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 condensed consolidated balance sheets for equity method investments for which it does not have a controlling interest in.

Results of Operations

Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations:

	FOR THE THREE MONTHS ENDED JUNE 30,		
(in thousands)	2022	2021	CHANGE
Operating expenses:			
Research and development	$ 10,138	$ 6,818	$ 3,320
General and administrative	7,477	3,712	3,765
Total operating expenses	17,615	10,530	7,085
Loss from operations	(17,615)	(10,530)	(7,085)
Total other income (expense), net:	370	(129)	499
Loss from continuing operations	(17,245)	(10,659)	(6,586)
Loss on investment in joint venture	338	468	(130)
Net loss	$ (17,583)	$ (11,127)	$ (6,456)

Operating Expenses

Research and Development Expenses

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

(in thousands)	THREE MONTHS ENDED JUNE 30, 2022	2021	CHANGE
Direct research and development by program			
RLYB211	$ 79	$ 519	$ (440)
RLYB212	2,106	3,026	(920)
RLYB116	903	1,341	(438)
RLYB114	493	514	(21)
Other program candidates	47	(331)	378
Asset acquisitions IPR&D expense	3,073	—	3,073
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	3,303	1,549	1,754
Other expenses	134	200	(66)
Total research and development expenses	$ 10,138	$ 6,818	$ 3,320

Research and development expenses were $10.1 million for the three months ended June 30, 2022, compared to $6.8 million for the three months ended June 30, 2021. The increase of $3.3 million for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was primarily due to:

- a $3.1 million increase in asset acquisition IPR&D expense related to the second quarter 2022 acquisition of the worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331; and
- a $1.8 million increase in personnel expenses, including share-based compensation expense, primarily due to an increase in research and development related headcount in 2022.

This increase was partially offset by:

- a $0.9 million and a $0.4 million decrease related to the development of RLYB212 and RLYB116, respectively, primarily attributable to a decrease in clinical manufacturing expenses; and
- a $0.4 million decrease in costs related to the development of RLYB211 as we continue to develop our lead product candidate, RLYB212.

General and Administrative Expenses

General and administrative expenses were $7.5 million for the three months ended June 30, 2022, compared to $3.7 million for the three months ended June 30, 2021. The increase of $3.8 million is primarily related to an increase in payroll and personnel-related costs due to an increase in general and administrative related headcount, including an increase of $1.4 million in share-based compensation, an increase in other professional fees, costs associated with operating as a public company and an increase in business development supporting expenses.

Total Other Income (Expense), Net

Total other income (expense), net, for the three months ended June 30, 2022 was income of $0.4 million compared to an expense of $0.1 million for the three months ended June 30, 2021. The change was due to an increase in interest income of $0.5 million primarily related to an increase in interest income from marketable securities.

Loss On Investment In Joint Venture

Loss on investment in joint venture for the three months ended June 30, 2022 was $0.3 million compared to $0.5 million for the three months ended June 30, 2021.

Results of Operations

Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations:

(in thousands)	FOR THE SIX MONTHS ENDED JUNE 30, 2022	2021	CHANGE
Operating expenses:			
Research and development	$ 17,786	$ 15,855	$ 1,931
General and administrative	14,147	7,499	6,648
Total operating expenses	31,933	23,354	8,579
Loss from operations	(31,933)	(23,354)	(8,579)
Total other income (expense), net	580	(98)	678
Loss from continuing operations	(31,353)	(23,452)	(7,901)
Loss on investment in joint venture	728	950	(222)
Net loss	$ (32,081)	$ (24,402)	$ (7,679)

Operating Expenses

Research and Development Expenses

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

(in thousands)	SIX MONTHS ENDED JUNE 30, 2022	2021	CHANGE
Direct research and development by program			
RLYB211	$ 235	$ 1,262	$ (1,027)
RLYB212	4,597	6,935	(2,338)
RLYB116	1,521	3,934	(2,413)
RLYB114	1,720	524	1,196
Other program candidates	47	7	40
Asset acquisitions IPR&D expense	3,073	—	3,073
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	6,336	2,874	3,462
Other expenses	257	319	(62)
Total research and development expenses	$ 17,786	$ 15,855	$ 1,931

Research and development expenses were $17.8 million for the six months ended June 30, 2022, compared to $15.9 million for the six months ended June 30, 2021. The increase of $1.9 million in 2022 as compared to 2021 was primarily due to:

- a $3.1 million increase in asset acquisition IPR&D expense related to the second quarter 2022 acquisition of the worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331;
- a $1.2 million increase attributable to increased preclinical research and development costs and clinical manufacturing expenses to advance RLYB114; and
- a $3.5 million increase in personnel expenses, including share-based compensation expense, primarily due to an increase in research and development related headcount in 2022.

These increases were partially offset by:

- a $2.4 million and a $2.3 million decrease related to the development of RLYB116 and RLYB212, respectively, primarily attributable to a decrease in clinical manufacturing expenses; and
- a $1.0 million decrease in costs related to the development of RLYB211 as we continue to develop our lead product candidate, RLYB212.

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

General and Administrative Expenses

General and administrative expenses were $14.1 million for the six months ended June 30, 2022, compared to $7.5 million for the six months ended June 30, 2021. The increase of $6.6 million is primarily related to an increase in payroll and personnel-related costs due to an increase in general and administrative related headcount, including an increase of $2.4 million in share-based compensation, an increase in other professional fees, costs associated with operating as a public company and an increase in business development supporting expenses.

We anticipate that our general and administrative expenses will continue to increase as we increase headcount that provide administrative support to our research and development activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses associated with operating as a public company for a full year in 2022 as compared to 2021.

Total Other Income (Expense), Net

Total other income (expense), net, for the six months ended June 30, 2022 was income of $0.6 million compared to an expense of $0.1 million for the six months ended June 30, 2021. The change was due to an increase in interest income of $0.7 million from marketable securities.

Loss On Investment In Joint Venture

Loss on investment in joint venture for the six months ended June 30, 2022 was $0.7 million compared to $1.0 million for the six months ended June 30, 2021.

Liquidity and Capital Resources

Sources of Liquidity

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 7,130,000 shares of common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs paid by us.

As of June 30, 2022, we had $147.4 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 into the first quarter of 2024. The Company has implemented cash preservation initiatives including reviewing certain discretionary expenses and managing the timing of certain future preclinical development activities. These initiatives do not impact the future clinical development plans for RLYB212 or RLYB116. This estimate and our expectation to advance the preclinical and clinical development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate.

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

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

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

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

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

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

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We currently have no credit facility or committed sources of capital. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Cash Flows

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

(in thousands)	FOR THE SIX MONTHS ENDED JUNE 30, 2022	2021
Net cash used in operating activities	$ (27,285)	$ (24,775)
Net cash used in investing activities	(87,296)	(2,066)
Net cash used by financing activities	—	(663)
Net decrease in cash and cash equivalents	$ (114,581)	$ (27,504)

Operating Activities

During the six months ended June 30, 2022, net cash used in operating activities was $27.3 million as compared to $24.8 million for the six months ended June 30, 2021. The increase in cash used in operating activities was primarily due to an increase in general and administrative expenses related to our increase in headcount and the costs of operating as a public company as compared to the six months ended June 30, 2021, and an increase in research and development primarily related to IPR&D expenses associated with the acquisition to obtain worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331 as compared to the six months ended June 30, 2021.

Investing Activities

Net cash used in investing activities was $87.3 million for the six months ended June 30, 2022 as compared to $2.1 million for the six months ended June 30, 2021. The increase in net cash used in investing activities was primarily related to the purchases of highly rated debt securities as compared to the six months ended June 30, 2021.

Financing Activities

No cash was provided or used in financing activities for the six months ended June 30, 2022 as compared to $0.7 million for the six months ended June 30, 2021, representing payments for offering costs related to our IPO of $0.7 million.

Contractual Obligations

There have been no other material changes in our contractual obligations and commitments during the six months ended June 30, 2022 from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations" in our Annual Report other than the contractual obligations resulting from the RLYB331 program. In May 2022, we obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, a preclinical potentially first-in-class antibody. Under the terms of the license agreement, we made an upfront payment of $3.0 million 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 milestone payments and up to an aggregate of $150.0 million in commercial milestone payments 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our unaudited condensed 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 condensed 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.

For a complete discussion of our significant accounting policies and recent accounting pronouncements, see Note 2 to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and Note 2 to our Annual Report. We believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our unaudited condensed 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.

Emerging Growth Company and Smaller Reporting Company

As an emerging growth company (an “EGC”) under the Jumpstart Our Business Startups Act (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 initial public offering, 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 condensed 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 June 30, 2022 and December 31, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide the information under this item.

Item 4. 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 June 30, 2022. 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 June 30, 2022, 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.

Management's Report on Internal Control over Financial Reporting.
This Quarterly Report on Form 10-Q does not include a report of management's assessment regarding our internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act, or an attestation report of our independent registered accounting firm due to a transition period established by rules of the Securities Exchange Commission for newly public companies.

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.

PART II—OTHER INFORMATION

Item 1. 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 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes appearing in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report, and the section of this Quarterly Report on Form 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Some of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic (including any resurgences thereof) and any worsening of the global business and economic environment as a result. Negative consequences from these risks could harm our business, prospects, operating results and financial condition or cause the trading price of our common stock to decline. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the

commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a limited operating history. As a result, we are not profitable and have incurred significant losses since our formation. We had net losses of $47.0 million and $26.4 million for the years ended December 31, 2021 and 2020, respectively, net losses of $17.6 million and $11.1 million for the three months ended June 30, 2022 and 2021, respectively and $32.1 million and $24.4 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $126.1 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our programs and our Phase 1/2 clinical trial for RLYB211 and Phase 1 clinical trials for RLYB212 and RLYB116. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

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

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

We do not know when or whether we will become profitable. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates and to obtain the necessary regulatory approvals for their commercialization, which is subject to substantial additional risks and uncertainties, as described under “— Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval.” Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur net losses and negative cash flows in the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital. The amount of our future net losses will depend, in part, on

the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through current or future collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we successfully commercialize RLYB212, RLYB116 or any of our other product candidates, we may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis or meet outside expectations for our profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, execute our business plan or continue our operations.

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

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

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of June 30, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. This estimate and our expectation to advance the preclinical and clinical development of RLYB212, RLYB116 and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate. Changing circumstances, including any unanticipated expenses, could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because of the numerous risks and uncertainties, the length of time and scope of activities associated with development of RLYB212, RLYB116 or any product candidate we may develop is highly uncertain, we are unable to estimate the actual amount of funds we will require for development, approval and any approved marketing and commercialization activities. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including our ongoing Phase 1/2 clinical trial for RLYB211 and Phase 1 and Phase 1b clinical trials for RLYB212 and RLYB116, and the development of any other product candidates;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, and other comparable foreign regulatory authorities, including any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for RLYB212 or any other product candidates, including design, manufacturing and regulatory approval;
- the cost of filing, prosecuting, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- our ability to develop and commercialize products that are considered medically and/or financially differentiated to competitive products by physicians, patients and payers;
- the cost and timing of completion of commercial-scale manufacturing activities;

- the cost of making royalty, milestone or other payments under any future in-license agreements;
- our ability to maintain our collaboration with Exscientia on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies;
- the severity, duration and impact of the COVID-19 pandemic, which may adversely impact our business;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- the initiation, progress and timing of our commercialization of RLYB212 and RLYB116, if approved, or any other product candidates;
- the availability of third-party coverage and reimbursement for and pricing of any approved products; and
- the costs of operating as a public company.

We will require significant additional capital to advance the development and potential commercialization of our product candidates, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Depending on our business performance, the economic climate and market conditions, we may be unable to raise additional funds when needed on acceptable terms, or at all. Moreover, the effects of the COVID-19 pandemic continues to impact the global economy and a severe or prolonged economic downturn as a result of the COVID-19 pandemic could result in a variety of challenges for our business, including disruptions in the financial markets, which could adversely impact our ability to raise additional capital when needed or on acceptable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may need to significantly delay, scale back or discontinue the development of one or more of our product candidates or the commercialization of any product that may be approved for marketing, and we could be forced to discontinue operations. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

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

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

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

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

Rallybio was founded in January 2018 and our operations to date have been limited to financing and staffing our company, identifying, evaluating and acquiring or in-licensing product candidates and technologies, conducting preclinical studies and our clinical trials for RLYB211, RLYB212 and RLYB116, and preclinical studies for RLYB211, RLYB212, RLYB116 and RLYB114, and developing a pipeline of other preclinical and research programs. We have not yet demonstrated the ability to complete successfully a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future

success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing pharmaceutical products.

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

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

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Quarterly Report on Form 10-Q:

- variations in the level of expense related to the ongoing development of our product candidates or research pipeline;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing and commercializing our product candidates;
- our relationships, and any associated exclusivity terms, with strategic collaborators;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements, or the termination or modification of any such existing or future arrangements;
- our operation in a net loss position in the foreseeable future;
- our ability, ourselves or with collaborators, to develop a companion diagnostic, if required, and obtain marketing approval;
- our ability to consistently manufacture our product candidates, including in sufficient quantities for clinical or commercial purposes;
- our dependence on, and the need to attract and retain, key management and other personnel;
- developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain and maintain patent protection for our product candidates;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- business interruptions such as power outages, strikes, civil unrest, wars, acts of terrorism or natural disasters;
- potential advantages that our competitors and potential competitors may have in developing and commercializing competing technologies or products, securing funding for or obtaining the rights to critical intellectual property;
- regulatory developments affecting our product candidates or those of our competitors; and
- our ability to use our net operating loss ("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 except that, under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), federal NOLs generated in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the taxable year in which the loss arises. Additionally, the deduction for NOLs arising in taxable years beginning after December 31, 2017 is generally limited to 80% of current year taxable income, however, as a result of the CARES Act, for taxable years beginning before January 1, 2021, the deductibility of federal NOLs generated in taxable

years beginning after December 31, 2017 is not so limited. We also have substantial federal and state research and development and other tax credit carryforwards. 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. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. 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, and Regulatory Approval

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

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

- **Preclinical studies and clinical trials:** The impact of COVID-19 may cause delays and disruptions to some of our preclinical studies and clinical trials. The response to COVID-19 by healthcare providers may delay site initiation, may slow down enrollment and make the ongoing collection of data for patients enrolled in trials more difficult or intermittent. In addition, some participants and clinical investigators may be unable or unwilling to comply with clinical trial protocols. For example, quarantines or other travel limitations have been implemented in many countries and across the United States that may impede participant movement, affect sponsor access to study sites, and/or interrupt healthcare services, which may negatively impact the execution of clinical trials. We initiated a global natural history study for FNAIT in September 2021 that requires screening a large number of potential participants, as well as clinical trials for RLYB212 and RLYB116, and we could experience delays in screening due to COVID-19. Significant delays or disruptions to our preclinical studies or clinical trials could adversely affect our ability to timely initiate studies, conduct successful studies, generate scientifically robust clinical data, obtain regulatory approvals or commercialize our product candidates.
- **Manufacturing and supply:** We have encountered only limited disruptions to our manufacturing and supply chain as a result of COVID-19 to date, which have not had a material adverse impact on our business, but significant or prolonged disruptions could materially impact our business, operations or financial results. Even if our manufacturing operations are not materially disrupted, pandemic-related disruptions in other businesses, such as shipping and logistics companies, could affect the availability of our product candidates for our preclinical studies and clinical trials.
- **Operations:** In accordance with direction from state and local government authorities to protect the health of our employees, their families, and our communities, we made several changes to our operations in response to COVID-19. This response included performing all office-based work outside of the office. Our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, remote working could increase our cyber security risk. Government authorities could impose further restrictions, including mandated shutdown of businesses, which may negatively affect our operations.
- **Stock Price:** The extent and duration of the impact of the COVID-19 pandemic on our stock price is uncertain. The COVID-19 pandemic may cause our stock price to be more volatile, and our ability to raise capital could be impaired.

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

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

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

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

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

In addition, we submitted a CTA in Germany for RLYB212 in July 2021 and we initiated a Phase 1 first-in-human trial in Germany in the fourth quarter of 2021, with proof of concept data from a subsequent Phase 1b trial expected in the first quarter of 2023. Any delays in the advancement of our Phase 1 or Phase 1b trials for RLYB212 could impact our product development timelines, result in increased costs, affect our ability to obtain marketing approval for RLYB212 according to our plans, and delay commercialization.

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

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

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

Commercialization of product candidates we may develop will require additional preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA; obtaining manufacturing supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. The success of

our most advanced product candidates and other product candidates will depend on several factors, including the following:

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

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

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

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

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

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

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

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

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

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

We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned preclinical studies or clinical trials, will begin on time, need to be redesigned, enroll an adequate number of patients on time, or be completed on schedule, or at all. We may experience numerous unforeseen events that could delay or prevent our ability to complete current clinical trials or initiate and complete new trials, any of which may delay or prevent us from receiving marketing approval or commercializing our product candidates. These events include, but are not limited to:

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

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board ("DSMB") for such trial. Such authorities may impose a suspension or termination or recommend an alteration to clinical trials due to several factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, the identification of safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions. Furthermore, we rely and will rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled "— Risks Related to Our Dependence on Third Parties."

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

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

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

products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

- the design of the clinical trial, including the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or medical devices that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions, particularly for RLYB116;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- other factors we may not be able to control, such as the ongoing COVID-19 pandemic that may limit patients, principal investigators or staff, or clinical site availability.

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

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

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

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

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

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

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

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

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

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

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

- regulatory authorities may suspend or withdraw approvals of such product candidate;

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

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

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

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

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

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

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

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

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

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

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

Our product candidates target rare diseases and conditions, and the market opportunities for RLYB212, RLYB116 or any of our other product candidates, if approved, may be smaller than we anticipate. As a result, our commercial opportunity may be limited and because the target populations of our product candidates are for rare

diseases, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

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

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

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

If safe and effective use of RLYB212 or any of our other product candidates depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that test, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of development and approval of such diagnostic is time consuming and costly. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA, EMA and other comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro diagnostic tests intended to select the patients who will respond to a product candidate to obtain a pre-market approval ("PMA") simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the applicant must prepare and provide FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.

Given our limited experience in developing and commercializing in vitro diagnostic devices, including companion diagnostic tests, we do not plan to develop such tests internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these in vitro diagnostic tests. We may not be able to enter into arrangements with a provider to develop screening and/or diagnostic tests for use in connection with

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

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

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

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

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

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

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

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

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

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In April 2021, the FDA released additional guidance on its handling of inspections during the COVID-19 pandemic, addressing situations where the FDA may request to conduct a remote interactive evaluation. While participation in a remote interactive evaluation is voluntary, declining the FDA's guidance could impede the FDA's ability to make a timely regulatory decision (e.g., regarding adequacy of a clinical trial used in support of a pending application or adequacy of a drug manufacturing operation described in the application). Additionally, in July 2021, the FDA transitioned to the "base-case scenario" in its "Resiliency Roadmap for FDA Inspectional Oversight," where the FDA will move to standard operational levels for domestic surveillance inspections, though there was another pause in domestic inspectional activities in early 2022 as a result of the COVID-19 Omicron variant, which was lifted on February 7, 2022. Regulatory authorities outside the United States may also impose similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

Even if we obtain regulatory approval for any of our product candidates, we will still face extensive and ongoing regulatory requirements and obligations and continued regulatory review, which may result in significant

additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product candidates.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval preclinical and clinical testing, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice ("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 Federal Food, Drug and Cosmetic Act (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 RLYB212 or RLYB116, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize these product candidates. Any new post-marketing adverse events may significantly impact our ability to market the drugs and may require that we recall and discontinue commercialization of the products. Furthermore, if any confirmatory post-marketing trial fails to confirm the clinical profile or clinical benefits of RLYB212 or RLYB116, the FDA may withdraw its approval, which would materially harm our business.

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

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

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

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

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

In the European Union, (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 marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that can substantiate the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

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

Regulatory authorities in some jurisdictions, including the United States and the EU may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan

drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of more than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products evaluates, and the European Commission grants, an orphan drug designation principally to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In addition, the product under consideration is indicated for a condition where there exists no satisfactory method of diagnosis, prevention or treatment authorized in the EU or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. Each of the FDA and the European Commission has granted orphan drug designation for RLYB211 and RLYB212 for the treatment of FNAIT. We may seek orphan drug designation in the United States and the EU for our other product candidates but may be unsuccessful in doing so. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will consider orphan designation for any indication for which we apply or re-apply, or that we will be able to maintain such designation. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

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

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

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

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

In the United States, RLYB211 and RLYB212 have received designation from the FDA as rare pediatric disease drug products. Receipt of rare pediatric disease designation is a prerequisite to qualifying for receipt of a rare pediatric disease priority review voucher upon approval of a marketing application for the rare pediatric disease drug product. The priority review voucher may be used to obtain priority review of a future marketing application that would not otherwise qualify to receive priority review. Priority review shortens the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or NDA from the date of filing. As an alternative to using the priority review voucher to obtain priority review of one of its own marketing applications, the sponsor of a rare pediatric disease drug product receiving a priority review voucher may also sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

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

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

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

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

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the coverage determination process is often a

time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and reimbursement will be obtained or will be consistent across payors. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") was enacted as part of the Patient Protection and Affordable Care Act (the "ACA") to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based

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

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

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

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

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

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

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

In order to market and successfully commercialize any product candidates we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. If we commercialize any of our product candidates that may be approved ourselves, we will need to develop an in-house marketing organization and sales force across rare disease therapeutic areas, which will require significant expenditures, management resources, and time. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retrain marketing and sales personnel. Any failure or delay in the development of a

product candidate that affects the expected timing of commercialization of the product candidate or results in the failure of the product candidate to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses. Our investment would be lost if we are unable to retain or reposition our sales and marketing personnel.

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

Risks Related to Our Dependence on Third Parties

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

We acquired all rights to RLYB211 and RLYB212 from Prophylix in 2019 and rights to RLYB116 and RLYB114 from Sobi in 2019. We also obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, and have entered into joint ventures with Exscientia for the development of small molecule therapeutics for rare diseases. An important component of our approach to product development is to acquire or in-license rights to product candidates, products or technologies, acquire other businesses or enter into collaborations with third parties. We may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions, in-licenses or collaborations may not strengthen our competitive position, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to incur debt in connection with an acquisition, or in-license or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

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

- a collaborator may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale, or downsizing;
- a collaborator may seek to renegotiate or terminate its relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator may cease development in therapeutic areas that are the subject of our collaboration;
- a collaborator may not devote sufficient capital or resources towards our product candidates, or may fail to comply with applicable regulatory requirements;
- a collaborator may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our product candidates;
- a collaborator with commercialization obligations may not commit sufficient financial resources or personnel to the marketing, distribution, or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaborator may terminate a strategic alliance;

- a dispute may arise between us and a collaborator concerning the research, development, or commercialization of a product candidate resulting in a delay in milestones or royalty payments or termination of the relationship and possibly resulting in costly litigation or arbitration, which may divert management's attention and resources; and
- a collaborator may use our products or technology in such a way as to invite litigation from a third-party.

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

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

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

As of June 30, 2022, we had 45 full-time employees, upon whom we rely for various administrative, research and development, business development and other support services shared among our subsidiaries and the Exscientia joint venture. The size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries and the Exscientia joint venture, including their research and development activities, the management of financial, accounting, and reporting matters, and the oversight of our third-party vendors and partners. If our centralized team or our third party vendors and partners performing such functions fail to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

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

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these or other laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to

comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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

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

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

- the possible breach of the manufacturing agreement by the third-party;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- reliance on the third-party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
- the possible inability of third-party suppliers to supply and/or transport materials, components and products to us in a timely manner as a result of disruptions to the global supply chain, including in connection with the COVID-19 pandemic.

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

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

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

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

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

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

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

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

We and our CROs will be required to comply with the GLP requirements for our preclinical studies and GCP requirements for our clinical trials. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors,

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

Our CROs, vendors and clinical trial investigators are not our employees, and we do not control whether they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs and other third parties involved in our preclinical studies and clinical trials, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs and other third parties involved in our trials do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidates that we develop. As a result, our financial results and the commercial prospects for any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

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

Risks Related to Healthcare Laws and Other Legal Compliance Matters

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

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

Beyond the ACA, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare, accelerated or advanced Medicare payments to healthcare providers and payments to providers for COVID-19-related expenses and lost revenues. Other reform efforts affect pricing or

payment for drug products. For example, subsequent to the ACA, the Medicaid Drug Rebate Program was subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. Additional reform efforts are likely. The Biden administration has focused on reforms that would address the high cost of drugs. In response to an Executive Order from President Biden, the Secretary of HHS issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. Drug pricing reforms were included in major legislation supported by President Biden in 2021 (which ultimately stalled) and President Biden addressed drug pricing reform in his 2022 State of the Union Address. Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, at the federal level, there have been administration initiatives, Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs.

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.

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

General legislative cost control measures may also affect reimbursement for our product candidates. 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 2031 (except May 1, 2020 to March 31, 2022) 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.

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

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

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

- U.S. federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual

for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- U.S. 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;
- U.S. FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to 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; 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 Foreign Corrupt Practices Act ("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 General Data Protection Regulation (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 European Economic Area ("EEA") (including health data). See “—Our business operations may subject us to data protection laws, including the GDPR, the United Kingdom GDPR, the California Consumer Privacy Act ("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 United Kingdom GDPR, the CCPA and other similar laws.

The GDPR applies to companies established in the EEA, as well as to companies that are not established in the EEA and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. If we conduct clinical trial programs in the EEA (whether the trials are conducted directly by us or through a clinical vendor or collaborator), or enter into research collaborations involving the monitoring of individuals

in the EEA, or market our products to individuals in the EEA, we will be subject to the GDPR. The GDPR puts in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a concise, intelligible and easily accessible form), an individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA, short timelines for data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches, and limitations on retention of information. The GDPR also puts in place increased requirements pertaining to health data and other special categories of personal data, as well as a definition of pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third-party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros or up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

We may also have to comply with the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law following "Brexit." The UK GDPR mirrors the fines under the GDPR with fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term. On June 28, 2021 the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the United Kingdom to the United States. Most recently, on July 16, 2020, the Court of Justice of the European Union ("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. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. On June 4, 2021, the European Commission released two revised sets of standard contractual clauses, which have been designed in part to assist organizations in meeting the requirement of the CJEU's judgment. However, it is unclear how the use of these clauses will be scrutinized and enforced by supervisory authorities and privacy interest groups, and the process of entering into agreements with new standard contractual clauses, and updating our existing agreements that contain the previous clauses, may lead to additional costs and increase our overall risk exposure.

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

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the

implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. While we do not believe that we are directly subject to HIPAA as either a "covered entity" or "business associate," U.S. sites at which we conduct clinical trials are likely to be covered entities and thus must ensure that they obtain adequate patient authorization or establish another basis under HIPAA to disclose a clinical trial subject's individually identifiable health information to us and other entities participating in our clinical trials.

In the United States, the CCPA came into effect in January 2020 and, among other things, requires new disclosures to California individuals and affords such individuals new abilities to opt out of certain sales of personal information, and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Because we have not yet generated revenue and do not meet the CCPA's other jurisdictional tests, we do not yet meet the applicable threshold for 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. Further, the California Privacy Rights Act was approved by California voters in 2020, and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, though the obligations for covered businesses will apply to any personal information collected after January 1, 2022. Similar laws have been proposed or passed at the U.S. federal and state level, including the Virginia Consumer Data Protection Act, which will take effect on January 1, 2023, the Colorado Consumer Protection Act, which will take effect on July 1, 2023, the Connecticut Data Privacy Act, which will take effect on July 1, 2023, and the Utah Consumer Privacy Act, which will take effect on December 31, 2023. We expect to be subject to additional privacy laws at both the U.S. state level and abroad, as many jurisdictions worldwide in addition to those examples described above have either recently passed data privacy legislation or are considering enacting such legislation. 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, fraud and reporting laws may prove time-consuming and costly.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

The patent rights of pharmaceutical and biotechnology companies generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged in the U.S. or in numerous foreign jurisdictions. Various courts, including the United States Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter. Precisely what constitutes a law of nature or abstract idea is uncertain, and certain aspects of our technology could be considered ineligible for patenting under applicable law. In addition, the scope of patent protection outside the United States is uncertain, and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law precludes the patentability of methods of treatment of the human body. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents that protect our technology and product candidates, in whole or in part, in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights.

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

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

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the

life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours during periods when commercial exclusivity would be valuable to us.

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

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

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

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

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

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law

by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

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

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

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

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

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

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In

addition, future litigation may be initiated by patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets.

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

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

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

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

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

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

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during

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

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

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

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

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

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

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

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

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

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- we or our license partners or current or future collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

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

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

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

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

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

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

Many of our employees were previously employed by Alexion (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.

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

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

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

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

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

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

Risks Related to 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.

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

Since the shares of our common stock were offered in our IPO in July 2021 at a price of $13.00 per share and through August 1, 2022, the closing price per share of our common stock has ranged from as low as $6.26 to as high as $23.40. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- the success of the development of companion diagnostics, if required, for use with our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;

- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- effects of public health crises, pandemics and epidemics, such as COVID-19;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following our IPO. 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 August 1, 2022, we have 32,131,970 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. Moreover, as of June 30, 2022 holders of up to an aggregate of 22,634,614 shares 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. We also registered an aggregate of 7,659,526 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 44% of our outstanding common stock as of August 1, 2022. 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 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 emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

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

Our amended and restated certificate of incorporation and amended and restated bylaws 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 of 1933 (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, 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. Additionally, on March 27, 2020, President Trump signed into law the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. There also may be technical corrections legislation or other legislative changes proposed with respect to the TCJA and CARES Act, the effects of which cannot be predicted and may be adverse to us or our stockholders. Future changes in tax laws could have a material adverse effect on our business, cash flows, financial condition or results of operations. In particular, proposed tax legislation, including the proposed Build Back Better Act in the United States could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

The use of any product candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of clinical trial and product liability claims. Clinical trial or product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, clinical trial or product liability claims may result in:

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

The clinical trial and product liability insurance we currently carry, and any additional clinical trial and product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful clinical trial or product liability claim, or series of claims, brought against us could

cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any product candidates we develop.

Unfavorable global economic conditions 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. A severe or prolonged economic downturn, period of sustained increased inflation, 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 U.S. may also impact our operations or affect global markets, such as the recent invasion of Ukraine by Russia. While we do not currently conduct clinical trials in the Ukraine or Russia, 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. Similarly, the volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets. A weak or declining economy could 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 Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds

On August 2, 2021, we completed the IPO of our common stock pursuant to which we issued and sold 7,130,000 shares of our common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $13.00 per share. The aggregate offering price of the IPO was $92.7 million.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-257655), which was declared effective by the SEC on July 28, 2021 and a registration statement on Form S-1MEF (File No. 333-258244), which was automatically effective upon filing with the SEC on July 28, 2021. Following the sale of all of the shares offered in connection with the closing of our IPO, the offering terminated. Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. acted as co-managers for the offering.

We received aggregate gross proceeds from our IPO of $92.7 million, or aggregate net proceeds of $83.0 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering costs were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

As of June 30, 2022, we had not used any of the net proceeds from the IPO. There has been no material change in our planned use of the net proceeds from the IPO as described in the IPO Prospectus, other than that a portion of the net proceeds may be used for preclinical development of RLYB331.

Item 6. Exhibits.

Exhibit Number	Description
10.1*	License Agreement by and between Rallybio IPE, LLC and Kymab Limited, dated as of May 5, 2022.
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.
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.

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: August 8, 2022

By: /s/ Martin W. Mackay

Martin W. Mackay, Ph.D.
Chief Executive Officer and Director (Principal Executive Officer)

Date: August 8, 2022

By: /s/ Jeffrey M. Fryer

Jeffrey M. Fryer, CPA
Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)

EXECUTION VERSION

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) the registrant customarily and actually treats such information as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

LICENSE AGREEMENT

between

KYMAB LIMITED

and

RALLYBIO IPE, LLC

Dated as of May 5, 2022

Exhibit 10.1

EXECUTION VERSION

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Schedules

Schedule 1.8	Back-up Sequences
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Schedule 1.62	Licensed Product Patents
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Schedule 2.6	Transferred Materials
Schedule 3.1.2	Development Plan
Schedule 9.4	Initial Press Release

LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is made and entered into as of May 5, 2022 (the "**Effective Date**") by and between Kymab Limited, a corporation incorporated in the United Kingdom, having offices located at Bennet Building (B930), Babraham Research Campus, Cambridge, UK, CB22 3AT ("**Sanofi Kymab**" or "**Licensor**") and Rallybio IPE LLC, a Delaware limited liability company, having offices located at 234 Church Street, Suite 1020, New Haven, CT 06510 ("**Rallybio**" or "**Licensee**"). Sanofi Kymab and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Sanofi Kymab controls certain property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein); and

WHEREAS, Sanofi Kymab wishes to grant to Licensee, and Licensee wishes to be granted, a license under such property rights to Exploit (as defined herein) Licensed Products in the Territory, in each case, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**Accountant**" has the meaning set forth in Section 6.12 (Audit Dispute).

1.2. "**Accounting Standards**" means the then-current version financial reporting standards followed by Licensee, its Affiliate or Sublicensee, examples of which are IFRS (International Financial Reporting Standards) and GAAP (United States generally accepted accounting principles), in each case consistently applied.

1.3. "**Adverse Event**" means (a) the development of an undesirable medical condition or the deterioration of a pre-existing medical condition in a patient or clinical investigation subject during or following exposure to or use of a Licensed Product, whether or not considered causally related to such Licensed Product, (b) the exacerbation of any pre-existing condition occurring during or following exposure to or use of a Licensed Product, or (c) any other adverse experience or adverse drug experience (as described in the FDA's Investigational New Drug safety reporting and NDA post-marketing reporting regulations, 21 C.F.R. §§312.32 and 314.80, respectively, and any applicable corresponding regulations outside the United States, in each case as may be amended from time to time), occurring during or following exposure to or use of a Licensed Product. For purposes of this Agreement, "undesirable medical condition" includes symptoms (*e.g.*, nausea, chest pain), signs (*e.g.*, tachycardia, enlarged liver) or the abnormal results

of an investigation (*e.g.*, laboratory findings, electrocardiogram), including unfavorable side effects, toxicity, injury, overdose or sensitivity reactions.

1.4. "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.5. "**Agreement**" has the meaning set forth in the preamble hereto.

1.6. "**Alliance Manager**" has the meaning set forth in Section 13.2 (Alliance Managers).

1.7. "**Applicable Law**" means laws, statutes, rules, regulations, treaties (including tax treaties), orders, judgments or ordinances having the effect of law of any national, multinational, federal, state, provincial, county, city or other political subdivision, that are applicable to the performance of the relevant activities under this Agreement, including any rules, regulations, guidelines (including Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices, as respectively defined under the ICH Guidelines) or other requirements of the Regulatory Authorities that may be in effect from time to time.

1.8. "**Back-up**" means the specific anti-MTP2 monoclonal antibodies having the sequences listed in Schedule 1.8 (Back-up Sequences).

1.9. "**BLA**" has the meaning set forth in Section 1.33 (Drug Approval Application).

1.10. "**Breaching Party**" has the meaning set forth in Section 12.3 (Termination of this Agreement for Material Breach).

1.11. "**Business Day**" means a day other than (a) a Saturday or Sunday, or (b) any day on which banking institutions in Paris, France or New York, New York are closed.

1.12. "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.13. "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.

1.14. "**Change of Control**" means, with respect to a Party, (a) any sale, exchange, transfer, or issuance to or acquisition by one or more Third Parties of shares representing more than fifty percent (50%) of the aggregate ordinary voting power entitled to vote for the election of directors represented by the issued and outstanding stock of such Party or any Affiliate that directly or indirectly controls (as defined in Section 1.4 (Affiliate)) (such Affiliate, a "Parent" of such Party), whether such sale, exchange, transfer, issuance or acquisition is made directly or indirectly,

beneficially or of record or in one transaction or a series of related transactions, but excluding the issuance of shares in financing transactions, including any venture capital financing or any public offering; or (b) a merger or consolidation under Applicable Law of such Party with a Third Party in which the shareholders of a Party or such Parent immediately prior to such merger or consolidation do not continue to hold immediately following the closing of such merger or consolidation more than fifty percent (50%) of the aggregate ordinary voting power entitled to vote for the election of directors represented by the issued and outstanding stock of the entity surviving or resulting from such consolidation.

1.15. "**Clinical Studies**" means human clinical trials for a Licensed Product and any other tests and studies for a Licensed Product in human subjects.

1.16. "**Combination Product**" means a product composed of (a) any combination of a Licensed Product and a device; or (b) a Licensed Product together with one or more other products whose active ingredients is/are not Licensed Compounds (formulated or packaged either as a fixed dose or as separate doses), and wherein (a) and (b) are sold in a single package for a single price.

1.17. "**Commercialization**" means, with respect to a Licensed Product, any and all activities (whether before or after Market Approval) directed to the marketing, promotion and sale of such Licensed Product in the Field in the Territory after Market Approval for commercial sale has been obtained, including pre-launch and post-launch marketing, advertising, promoting, marketing research, distributing, offering to commercially sell and commercially selling such Licensed Product, importing, exporting or transporting such Licensed Product for commercial sale, medical education activities with respect to such Licensed Product, conducting Clinical Studies that are not required to obtain or maintain Market Approval for such Licensed Product for an indication, which may include epidemiological studies, modeling and pharmacoeconomic studies, post-marketing surveillance studies, investigator sponsored studies and health economics studies and regulatory affairs (including interacting with Regulatory Authorities) with respect to the foregoing. When used as a verb, "**Commercializing**" means to engage in Commercialization and "**Commercialize**" and "**Commercialized**" shall have a corresponding meaning.

1.18. "**Commercially Reasonable Efforts**" means [***].

1.19. "**Commercialization Reports**" has the meaning set forth in Section 12.3 (Commercialization Report).

1.20. "**Complaining Party**" has the meaning set forth in Section 12.3 (Termination of this Agreement for Material Breach).

1.21. "**Completion of Toxicity Studies**" means [***].

1.22. "**Confidential Information**" has the meaning set forth in Section 9.1 (Confidentiality Obligations).

1.23. "**Control**" means, with respect to any Know-How, Patent, or other property right, possession of the right by a Party, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2.1 (Grants)), to grant access, assign or grant a license, sublicense or other right to or under such

property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party or misappropriating trade secret information of a Third Party.

1.24. "**Controlling Party**" has the meaning set forth in Section 7.4.1 (Defense of Third Party Claims).

1.25. "**Derived Patent**" means any Patent filed by Licensee or its Affiliate or Sublicensee [***] the claims of which are [***] Licensed Know-How.

1.26. "**Development**" means, with respect to a compound or product (including new Indications and formulations of a compound or product), all activities related to research, development, preclinical and other non-clinical testing (including compound discovery), test method development and stability testing, toxicology, formulation, process development, quality, Clinical Studies (including Manufacturing in support thereof (but excluding any commercial Manufacturing)), statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Market Approval, in each case for such compound or product. When used as a verb, "**Develop**" means to engage in Development.

1.27. **"Development and Regulatory Milestone Events"** has the meaning set forth in Section 6.2 (Development and Regulatory Milestones).

1.28. **"Development and Regulatory Milestone Payments**" has the meaning set forth in Section 6.2 (Development and Regulatory Milestones).

1.29. "**Development Plan**" means the plan for the Development of the Licensed Products as described in Section 3.1.2, as updated from time to time pursuant to Section 3.1.2 (Development Plan).

1.30. "**Disclosing Party**" has the meaning set forth in Section 9.1 (Confidentiality Obligations).

1.31. "**Dispute**" has the meaning set forth in Section 13.6 (Dispute Resolution).

1.32. "**Dollars**" or "**$**" means United States Dollars.

1.33. "**Drug Approval Application**" or (**"DAA"**) means an authorization or approval to market a Licensed Product in a particular country or regulatory jurisdiction in the Territory, including a Biologics License Application (a "**BLA**") as defined in the United States *Public Health Service Act* ("**PHSA**") and the regulations promulgated thereunder (including all additions, supplements, extensions and modifications thereto), or any corresponding application in other jurisdictions in the Territory, including, with respect to the European Union, a Marketing Authorization Application (an "**MAA**") filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.34. "**Effective Date**" has the meaning set forth in the preamble hereto.

1.35. "**ELNs**" has the meaning set forth in Section 2.5 (Disclosure of Licensed Know-How).

1.36. "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.37. "**Europe**" means the countries comprising the European Economic Area as it may be constituted from time to time.

1.38. "**European Union**" **or "EU"** means the economic, scientific and political organization of member states as it may be constituted from time to time.

1.39. "**Executive Officer**" means a senior executive of a Party having corporate authority to make decisions regarding this Agreement.

1.40. "**Exploit**" means, with respect to a product, to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise exploit such product and "**Exploitation**" means the act of Exploiting a product.

1.41. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.42. "**FFDCA**" means the United States Food, Drug, and Cosmetic Act, as amended from time to time, and the rules and regulations promulgated thereunder.

1.43. "**Field**" means the prevention, diagnosis and/or treatment of any disease in humans, including without limitation, the treatment of diseases resulting from or in iron dysregulation.

1.44. "**First Commercial Sale**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale to a Third Party for monetary value for use or consumption by the general public of such Licensed Product in such country after the applicable Regulatory Authority has approved the Drug Approval Application for such Licensed Product in such country and for which any of Licensee or its Affiliates or Sublicensees has invoiced sales of Licensed Products in the Territory; provided, however, that the following shall not constitute a First Commercial Sale: (a) [***]; (b) Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensees, unless such Licensed Product is consumed by such Affiliate or Sublicensee in the course of its commercial activities; or (c) any use of such Licensed Product in Clinical Studies or non-clinical development activities with respect to such Licensed Product by or on behalf of a Party.

1.45. "**Force Majeure Event**" has the meaning set forth in Section 13.1 (Force Majeure).

1.46. "**Hatch-Waxman Act**" means the Drug Price Competition and Patent Term Restoration Act of 1984, as amended.

1.47. "**IND**" means an investigational new drug application filed with the FDA for authorization to commence Clinical Studies in the United States (including all additions,

amendments, supplements, extensions and modifications thereto), or any corresponding applications in other jurisdictions in the Territory.

1.48. "**Indemnification Claim Notice**" has the meaning set forth in Section 11.3 (Notice of Claim).

1.49. "**Indemnified Party**" has the meaning set forth in Section 11.3 (Notice of Claim).

1.50. "**Indemnifying Party**" has the meaning set forth in Section 11.3 (Notice of Claim).

1.51. "**Indication**" means any distinct human disease category, as evidenced by the filing of a separate Drug Approval Application (or supplemental Drug Approval Application, as the case may be).

1.52. "**Infringement**" has the meaning set forth in Section 7.3.1 (Notice).

1.53. "**Infringement Notice**" has the meaning set forth in Section 7.3.1 (Notice).

1.54. "**Inserm Agreement"** has the meaning set forth in Section 9.5 (Publications).

1.55. "**Invoiced Sales**" has the meaning set forth in the Section 1.75 (Net Sales).

1.56. "**Know-How**" shall mean technical or scientific information, know-how, data, results, protocols, techniques, discoveries, inventions, specifications, designs, trade secrets, improvements and other information, including marketing or supply information and data, and information and data included or referenced in a Regulatory Documentation, whether or not protected by trade secret under Applicable Law, whether or not patentable.

1.57. **"Licensed Anemia Patents**" means the Patents Controlled by Sanofi Kymab as of the Effective Date set forth on Schedule 1.57 (Licensed Anemia Patents).

1.58. "**Licensed Compound**" means the specific anti-MTP2 monoclonal antibody internally referred to by Sanofi Kymab as KY1066 whose sequence is listed in Schedule 1.58 (KY1066 Sequence), (b) [***], and (c) any [***] clauses (a) and (b) [***].

1.59. "**Licensed Know-How**" means the Know-How Controlled by Sanofi Kymab and its Affiliates as of the Effective Date set forth on Schedule 1.59 (Licensed Know-How).

1.60. "**Licensed Platform Patents**" means the Patents Controlled by Sanofi Kymab as of the Effective Date set forth on Schedule 1.60 (Licensed Platform Patents).

1.61. "**Licensed Product**" means any pharmaceutical product containing a Licensed Compound as an active pharmaceutical ingredient, in any form, formulation, dose, or presentation, alone or in combination with one or more other active ingredients.

1.62. "**Licensed Product Patents**" means the Patents Controlled by Sanofi Kymab as of the Effective Date set forth on Schedule 1.62 (Licensed Product Patents).

1.63. "**Licensee**" has the meaning set forth in the preamble hereto.

1.64. "**Licensee Indemnitees**" has the meaning set forth in Section 11.2 (Indemnification of Licensee).

1.65. "**Losses**" has the meaning set forth in Section 11.1 (Indemnification of Sanofi Kymab).

1.66. "**MAA**" has the meaning set forth in Section 1.33 (Drug Approval Application).

1.67. "**Major Markets**" has the meaning set forth in Section 3.2 (Development Diligence).

1.68. "**Manufacture**" and "**Manufacturing**" means, with respect to a product, all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, holding, stability testing, quality assurance or quality control of such product or any intermediate thereof.

1.69. "**Market Approval**" means an approval from a Regulatory Authority of the applicable Drug Approval Application for such Licensed Product by such Regulatory Authority.

1.70. "**Milestone Event**" means each of the Development and Regulatory Milestone Events identified as a milestone event in Section 6.2.1 (Development and Regulatory Milestones) and the Sales Milestone Events identified as a milestone event in Section 6.2.2 (Sales Milestones).

1.71. "**Milestone Payment**" means each of the Development and Regulatory Milestone Payments identified in Section 6.2.1 (Development and Regulatory Milestones) and the Sales Milestone Payments identified in Section 6.2.2 (Sales Milestones).

1.72. "**Monetization**" means the monetization of all or a portion of Sanofi Kymab's rights to receive royalties and other related payments under this Agreement, including by means of a direct sale (through an auction process or otherwise) or a financing (through a borrowing of loans, an offering of securities or otherwise).

1.73. **"MTP2"** means matriptase-2.

1.74. **"National Phase Entry"** has the meaning set forth in Section 7.2.1 (Licensed Product Patents).

1.75. "**Net Sales**" means, for any period, the gross amount invoiced by Licensee or any of its Affiliates or Sublicensees for the sale of a Licensed Product (the "**Invoiced Sales**"), less deductions for: (a) [***].

[***].

[***].

Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Licensed Product is consumed by such Affiliate or Sublicensee in the course of its commercial activities.

1.76. "**Non-Controlling Party**" has the meaning set forth in Section 7.4.1 (Defense of Third Party Claims).

1.77. **"NPE Counsel Transfer Date"** has the meaning set forth in Section 7.2.1 (Licensed Product Patents).

1.78. "**NPE Countries"** has the meaning set forth in Section 7.2.1 (Licensed Product Patents).

1.79. **"NPE Transfer Date"** has the meaning set forth in Section 7.2.1 (Licensed Product Patents).

1.80. "**Party**" and "**Parties**" each has the meaning set forth in the preamble hereto.

1.81. "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed from any of the foregoing provisional patent applications in clause (a), (c) all patent applications that claim priority to any patent or patent applications in clause (a) or clause (b), including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (d) any and all patents that have issued or in the future issue from any of foregoing patent applications in clause (a), clause (b) or clause (c), including utility models, petty patents and design patents and certificates of invention, and (e) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of any of the foregoing patents or patent applications in clause (a), clause (b), clause (c) or clause (d).

1.82. "**Payments**" has the meaning set forth in Section 6.8 (Taxes).

1.83. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.84. "**Phase 1 Clinical Study**" means a Clinical Study of a Licensed Product (or the portion thereof in the case of a Phase 1/2 Clinical Study) that meets the definition of a Phase 1 study in the Clinical Trial Regulation EU No 536/2014 and for the United States as described in 21 C.F.R. §312.21(a), or its successor regulation, or the equivalent regulation in any other country

1.85. "**Phase 2 Clinical Study**" means a Clinical Study of a Licensed Product (or the portion thereof in the case of a Phase 1/2 Clinical Study or Phase 2/3 Clinical Study) that meets the definition of a Phase 2 study in the Clinical Trial Regulation EU No 536/2014 and for the United States as described in 21 C.F.R. §312.21(b), or its successor regulation, or the equivalent regulation in any other country.

1.86. "**Phase 3 Clinical Study**" means a Clinical Study of Licensed Product (or the portion thereof in the case of a Phase 2/3 Clinical Study) that meets the definition of a Phase 3 study in the Clinical Trial Regulation EU No 536/2014 and for the United States as described in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent regulation in any other country.

1.87. "**Priority Review**" means a review of a DAA by the applicable Regulatory Authority not later than six (6) months after the filing of DAA to such Regulatory Authority.

1.88. "**Priority Review Voucher**" or "**PRV**" means a priority review voucher granted by the U.S. Secretary of Health and Human Services that entitles the holder of such voucher to Priority Review of a single human drug application submitted under Section 505(b)(1) of the FFDCA or a single biologic application submitted under Section 351(a) of the PHSA.

1.89. "**Product Trademarks**" means the Trademark(s) to be used or that are used by Licensee or its Affiliates for the Commercialization of the Licensed Products in the Field in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any Trademarks that include any corporate name or logo of the Parties or their Affiliates).

1.90. "**Profit Sharing Arrangement**" means a transaction in which Licensee and a proposed Sublicensee would share responsibility for Development and/or Manufacturing and/or Commercialization of one or more Licensed Compounds and/or Licensed Products in a country or region of the Territory, in which the financial terms of such arrangement would include a pre-determined allocation of profits and losses for on sales of Licensed Products in such country or region), in addition to or in lieu of the payment of fees, milestones payments, royalties, and sharing of Sublicense Income, and which may also include cost sharing as between Licensee and the proposed Sublicensee with respect to their respective for Development and/or Manufacturing and/or Commercialization activities with respect to Licensed Compounds and/or Licensed Products.

1.91. "**Receiving Party**" has the meaning set forth in Section 9.1 (Confidentiality Obligations).

1.92. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Licensed Compound or a Licensed Product in the Territory.

1.93. "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including all Market Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, Adverse Event files and complaint files.

1.94. "**Regulatory Exclusivity**" means any period of data or market exclusivity granted or otherwise authorized in respect of a Licensed Product that prohibits a Person from (a) relying on safety or efficacy data generated by or on behalf of a Party with respect to such Licensed Product in an application for regulatory approval of a biosimilar product, or (b) Commercializing a Licensed Product, including any such period under the FFDCA, European Parliament and Council Regulations (EC) Nos. 726/2004, 141/2000 and 1901/2006, or national implementations of Article 10 of Directive 2001/83/EC, and all equivalents (in the United States, European Union or elsewhere) of any of the foregoing. A Patent is not a form of Regulatory Exclusivity.

1.95. "**Royalty Term**" means on a Licensed Product by Licensed Product and country-by-country basis, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country, and ending on the latest to occur of: (a) the expiration of last Valid Claim of a Licensed Product Patent or Derived Patent; (b) the loss (solely to the extent not arising from any act or omission of Licensee, its Affiliate, Sublicensee or any Person acting on behalf of any of the foregoing) or expiration of Regulatory Exclusivity in such country for such Licensed Product; and (c) the [***] of the First Commercial Sale of such Licensed Product in such country.

1.96. **"Sales Milestone Events"** has the meaning set forth in Section 6.2.2 (Sales Milestones).

1.97. **"Sales Milestone Payments"** has the meaning set forth in Section 6.2.2 (Sales Milestones).

1.98. "**Sanofi Kymab**" has the meaning set forth in the preamble hereto.

1.99. "**Sanofi Kymab Indemnitees**" has the meaning set forth in Section 11.1 (Indemnification of Sanofi Kymab).

1.100. "**Securities Regulator**" is defined in Section 9.2.1 (Permitted Disclosures).

1.101. "**Service Provider**" means a Third Party retained by Licensee, its Affiliate or Sublicensee, as applicable, to perform services on behalf of Licensee, its Affiliate or Sublicensee, as applicable.

1.102. "**Sublicense Agreement**" has the meaning set forth in Section 2.3

1.103. "**Sublicensee**" means a Third Party to whom a Licensee, its Affiliate or Sublicensee, as applicable, has granted a sublicense in accordance with Section 2.3 for such Third Party to Exploit the Licensed Compounds and/or Licensed Products, and which rights may be limited to Development, Manufacture and/or Commercialization, as applicable.

1.104. **"Sublicense Income**" means all non-royalty payments including upfront fees, annual or maintenance license fees, development and/or regulatory and/or sales milestones (net of any amount due to Sanofi Kymab under Section 6.2 (Milestones) [***] event), received by Licensee from a Third Party as consideration of the grant of a sublicense pursuant to a Sublicense Agreement, but excluding (a) [***].

1.105. "**Start**" means with respect to any Clinical Study the date upon which the first study subject receives a dose of any placebo, Licensed Product, or comparator product or adjunct therapy in such study.

1.106. "**Term**" has the meaning set forth in Section 12.1 (Term).

1.107. "**Termination Notice Period**" has the meaning set forth in Section 12.3 (Termination of this Agreement for Material Breach).

1.108. "**Territory**" means all the countries and territories of the world.

1.109. "**Third Party**" means any Person other than Sanofi Kymab, Licensee and their respective Affiliates.

1.110. "**Third Party Claims**" has the meaning set forth in Section 11.1 (Indemnification of Sanofi Kymab).

1.111. **"Third Party License"** has the meaning set forth in Section 6.3.2(ii) (Third Party License).

1.112. "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.113. **"Transfer Income**" means all non-royalty payments including upfront fees, annual or maintenance license fees, development and/or regulatory and/or sales milestones (net of any amount due to Sanofi Kymab under Section 6.2 (Milestones) [***]), received by Licensee from a Third Party as consideration of the assignment (but not the sublicense) of the rights granted herein, but excluding (a) [***].

1.114. "**Transferred Materials**" means the biological or chemical materials listed on Schedule 2.6 (Transferred Materials).

1.115. "**Upfront Payment**" has the meaning set forth in Section 6.1 (Upfront Payment).

1.116. "**Valid Claim**" means, with respect to a particular country, (a) any claim of an issued and unexpired Patent in such country that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country or (b) any claim of a pending Patent application that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; provided that the term "Valid Claim" shall exclude any such claim in such a pending application that has not been granted within seven (7) years following the earliest priority filing date for such claim (unless and until such claim is granted).

ARTICLE 2
GRANT OF RIGHTS

2.1. **Grants.** Subject to the other terms and conditions of this Agreement, Sanofi Kymab hereby grants to Licensee (a) an exclusive license (including with regard to Sanofi Kymab and its Affiliates) under the Licensed Product Patents to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory, (b) a non-exclusive license under the Licensed Platform Patents solely to Manufacture Licensed Compounds and Licensed Products, (c) a non-exclusive license to use the Licensed Know-How to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory and (d) a non-exclusive license under the Licensed Anemia Patents to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory.

2.2. Retention of Rights TC "2.2 Retention of Rights" \f C \l "2" . Sanofi Kymab retains on behalf of itself and its Affiliates: (a) the right to practice under the Licensed Platform Patents for all uses except to Manufacture Licensed Compounds and Licensed Products, (b) the right to practice under the Licensed Anemia Patents and (c) the right to use the Licensed Know-How and retain samples of Licensed Compounds in Sanofi Kymab's compound library for [***], other than to Exploit any Licensed Product in the Field and in the Territory.

2.3. Sublicenses TC "2.4 Sublicenses" \f C \l "2" . Licensee shall have the right to sublicense its rights granted under Section 2.1 (Grants) to any of its Affiliates or any Third Party; provided that Licensee would structure the material terms of any proposed sublicense agreement so as to be substantially aligned to the material terms of this Agreement including with regard to triggers and tiers of Milestones and royalties to facilitate coherent calculation of all payments to Sanofi Kymab from Licensee including Sublicense Income; and further provided that in the event that Licensee intends to enter into any sublicense agreement which includes a Profit Sharing Arrangement, Licensee may only do so with Sanofi Kymab's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Licensee will provide Sanofi Kymab with a copy of each sublicense agreement (a "**Sublicense Agreement**") within [***] Business Days of execution, which may be redacted of any terms not relevant or otherwise necessary to confirm that such Sublicense Agreement is generally consistent with the material relevant terms of this Agreement. Licensee shall, notwithstanding any sublicense granted under any Sublicense Agreement, remain liable to Sanofi Kymab under this Agreement. Licensee shall not structure any Sublicense Agreement, either alone or in connection with other assets owned or controlled by Licensee and/or its Affiliate in a single transaction or series of related transactions, in order to minimize or avoid making payment to Sanofi Kymab of Sublicense Income generated by granting a sublicense of its rights hereunder that is required to be paid in accordance with the terms of this Agreement. For clarity, the terms of a Sublicense Agreement shall be deemed to be aligned and generally consistent with the relevant terms of this Agreement if the applicable terms of the Sublicense Agreement do not materially diminish either Sanofi Kymab's rights and/or Licensee's obligations, hereunder. Further, if Rallybio seeks the consent of Sanofi Kymab to any Profit Sharing Arrangement or other Sublicense Agreement (including in circumstances when such consent is not otherwise required by this Agreement), Sanofi Kymab will not unreasonably withhold, condition or delay such consent, and Sanofi Kymab will use reasonable efforts to provide its response to such request for consent as soon as practicable after Licensee delivers notice requesting consent to Sanofi Kymab hereunder, but in any event Sanofi Kymab will respond to Licensee's notice requesting consent no later than [***] calendar days following receipt of such notice; provided that if such notice is received in the months of August or December, then Sanofi Kymab will respond to Licensee's notice requesting consent no later than [***] calendar days following receipt of such notice.

2.4. No Implied Rights TC "2.6 No Implied Rights" \f C \l "2" . Licensee and its Affiliates shall have no right, express or implied, with respect to any Patent, Know-How, materials, or other property Controlled by Sanofi Kymab or its Affiliates except as expressly provided in Section 2.1 (Grants).

2.5. Disclosure of Licensed Know-How.

2.5.1. Sanofi Kymab shall disclose and make available to Licensee the Licensed Know-How listed on Schedule 1.59 (Licensed Know-How) as of the Effective Date within [***] calendar days after the Effective Date by granting the Licensee download rights to the data room from which the Licensed Know-How may be accessed. Licensee shall complete its

download of such Licensed Know-How within [***] calendar days after having been granted download rights in accordance with the preceding sentence.

2.5.2. [***].

2.5.3. All Licensed Know-How will be provided in the format and the language in which it was created.

2.5.4. [***].

2.6. Transferred Materials. Sanofi Kymab will deliver [***] the inventory of Transferred Materials listed on Schedule 2.6 (Transferred Materials) in a single shipment within ninety (90) calendar days after having received from Licensee all information necessary to deliver such Transferred Materials to Licensee (including without limitation, the Licensee's preferred delivery address, contact name(s) and customs information), which Licensee shall provide to Sanofi Kymab within [***] calendar days after the Effective Date. Licensee shall pay Sanofi Kymab's invoice for all shipping costs, including insurance, customs duties and any transfer tax incurred in connection with the delivery of the Transferred Materials within [***] days of receipt thereof. Delivery of the Transferred Materials by Sanofi Kymab to Licensee shall not constitute a sale of the Transferred Materials. Licensee shall hold the Transferred Materials only as permitted under this Agreement as a bailee. Licensee may use the Transferred Materials solely to conduct non-clinical Development of Licensed Compounds and the Licensed Products. Sanofi Kymab's obligation to transfer the Transferred Materials pursuant to this Section 2.6 (Transferred Materials) is subject to any Third Party consent required in connection with such transfer, and if Licensee requests that the Parties seek such Third Party's consent, the Parties agree to cooperate to seek such consent in a timely manner. Licensee acknowledges that the consent of any Third Party may not be granted unless and until Licensee and such Third Party enter into a separate agreement regarding the use of the Transferred Materials.

2.7. Technical Assistance. Beginning on the Effective Date and continuing for [***] thereafter, Sanofi Kymab would answer Licensee's reasonable technical questions regarding the Licensed Compounds, Licensed Product Patents, Licensed Know-How, and Transferred Materials to the extent such expertise is available within Sanofi Kymab and its Affiliates. Such technical assistance would be provided for no more than [***] during such [***] period. Following expiry of the initial [***] period of technical assistance, Sanofi Kymab may, at its sole discretion provide additional technical assistance requested by Licensee regarding the Licensed Compounds, Licensed Product Patents, Licensed Know-How, and Transferred Materials for no more than [***] during a [***] period, unless a greater number of hours is otherwise agreed, and Licensee would pay Sanofi Kymab [***] per full time equivalent. Licensee shall pay Sanofi Kymab for such technical assistance within [***] days of receipt of Sanofi Kymab's invoice for such technical assistance. [***].

ARTICLE 3
DEVELOPMENT AND REGULATORY

3.1. Development.

3.1.1. In General. As between the Parties, Licensee has sole responsibility for Development of the Licensed Products in the Field in the Territory and such Development shall be at Licensee's own cost and expense.

3.1.2. Development Plan. An initial plan to Develop the Licensed Compounds and Licensed Products in the Field in the Territory is attached hereto as Schedule 3.1.2 (such plan and any updates thereto, the "**Development Plan**"). The Development Plan must contain sufficient detail as to unambiguously identify each of the Development or Regulatory Milestone Events that Licensee anticipates may be achieved during the next [***] months, *provided, that*, Sanofi Kymab agrees that the identification of a Development and Regulatory Milestone Event in the Development Plan and each Development report provided under Section 3.3 (Development Reports) is based on Licensee's then-current estimate of when such Development and Regulatory Milestone Event may be achieved. The Development Plan is the Confidential Information of Licensee.

3.2. Development Diligence. Licensee shall use Commercially Reasonable Efforts (itself or with or through its Affiliates and/or Sublicensees) to Develop and obtain Market Approval of at least one Licensed Product in at least one Indication in the Field in each of (i) the United States, (ii) any of France, Germany, Spain, or Italy, (iii) the United Kingdom, and (iv) Japan (collectively the "**Major Markets**").

3.3. Development Reports. Licensee shall deliver to Sanofi Kymab a written annual report of its Development activities no later than [***] days after the end of each Calendar Year, which report shall include (a) an update, if any, to the then-current Development Plan including anticipated dates by which each of the Development and Regulatory Milestone Events are anticipated to occur in such Calendar Year, (b) a detailed summary of Development activities conducted during the reporting period Calendar Year (c) a detailed summary of all planned pre-clinical studies, Clinical Studies and regulatory submissions, and (d) the date upon which [***] as applicable. Each such Development report is the Confidential Information of Licensee.

3.4. Subcontracting. Licensee may retain Service Providers to conduct Development activities on its behalf provided that (a) Licensee shall oversee the performance by its Service Providers of the subcontracted Development activities, (b) Licensee shall remain liable to Sanofi Kymab in accordance with the terms of this Agreement for the performance of all Development activities conducted on behalf of Licensee hereunder, despite any such subcontracting, and (c) any agreement pursuant to which Licensee retains any Service Provider to perform Development activities must be in writing and must not be inconsistent with the relevant provisions of this Agreement.

3.5. Compliance. Licensee shall perform (and shall cause its Affiliates, Sublicensees and Service Providers to perform) all of its Development activities in compliance with the terms of this Agreement and all Applicable Laws.

3.6. Regulatory Matters.

3.6.1. TC "3.2 Regulatory Matters" \f C \l "2" Regulatory Responsibilities. As between the Parties, Licensee shall be solely responsible for preparing, obtaining and maintaining Drug Approval Applications and any other Market Approvals and other submissions, and for conducting communications with the Regulatory Authorities, for any Licensed Product in the Territory at its cost and expense. As between the Parties, all Market Approvals in the Territory for any Licensed Product shall be owned by Licensee.

ARTICLE 4
COMMERCIALIZATION

4.1. In General. As between the Parties, Licensee has sole responsibility for Commercialization of the Licensed Products in the Field in the Territory and such Commercialization shall be at Licensee's own cost and expense.

4.2. Commercialization Reports. Licensee shall deliver to Sanofi Kymab a written annual report of its Commercialization activities (a "**Commercialization Report**"), which shall be delivered within [***] days after the end of each Calendar Year; provided however that the first such report shall not be due until after the end of the year in which the first Development and Regulatory Milestone Event is achieved. Each Commercialization Report shall include (a) a detailed summary of Commercialization activities conducted during the prior Calendar Year including the date of First Commercial Sale of any Licensed Product in any country in the Territory, and (b) a detailed summary of all Commercialization activities planned for the next Calendar Year, including the anticipated date of First Commercial Sale of any Licensed Product in any country in the Territory and forecast of Net Sales of Licensed Products for the current and next Calendar Year. Sanofi Kymab agrees that the identification of any First Commercial Sale date for Licensed Product in a country in the Territory in a Commercialization Report provided under this Section 4.2 is based on Licensee's then-current estimate of when and if such First Commercial Sale may occur. Licensee's Commercialization Reports shall be the Confidential Information of Licensee.

4.3. Commercial Diligence TC "4.3 Diligence" \f C \l "2" **.** Licensee shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in each Major Market for which Market Approval has been granted for such Licensed Product in the Field.

4.4. Compliance with Applicable Law TC "4.4 Compliance with Applicable Law" \f C \l "2" **.** Licensee shall, and shall cause its Affiliates and Sublicensees to, comply with all Applicable Law with respect to the Commercialization of the Licensed Products.

4.5. Sales and Distribution TC "4.5 Sales and Distribution" \f C \l "2" **.** As between the Parties, Licensee shall be solely responsible for invoicing and booking sales, establishing all terms of sale (including pricing and discounts) and warehousing and distributing the Licensed Products in the Field in the Territory and shall perform all related services, in each case, in a manner that does not violate the terms and conditions of this Agreement. Licensee shall be solely responsible for handling all returns, recalls and withdrawals, order processing, invoicing and collection, distribution and inventory and receivables with respect to the Licensed Product in the Territory.

4.6. Subcontracting. Licensee may retain Service Providers to conduct Commercialization activities on its behalf provided that (a) Licensee shall oversee the performance by its Service Providers of the subcontracted Commercialization activities, (b) Licensee shall remain liable to Sanofi Kymab in accordance with the terms of this Agreement for the performance of all Commercialization activities conducted on behalf of Licensee hereunder, despite any such subcontracting, and (c) any agreement pursuant to which Licensee retains any Service Provider to perform Commercialization activities must be in writing and must not be inconsistent with the relevant provisions of this Agreement.

ARTICLE 5
MANUFACTURE AND SUPPLY

5.1. In General. As between the Parties, Licensee has sole responsibility for Manufacture, including to have Manufactured, its entire supply of the Licensed Compounds and Licensed Products at its own cost and expense.

5.2. Subcontracting. Licensee may retain Service Providers to conduct Manufacturing activities on its behalf provided that (a) Licensee shall oversee the performance by its Service Providers of the subcontracted Manufacturing activities, (b) Licensee shall remain liable to Sanofi Kymab in accordance with the terms of this Agreement for the performance of all Manufacturing activities conducted on behalf of Licensee hereunder, despite any such subcontracting, and (c) any agreement pursuant to which Licensee retains any Service Provider to perform Manufacturing must be in writing and must not be inconsistent with the relevant provisions of this Agreement.

5.3. Compliance. Licensee shall perform (and shall cause its Affiliates, Sublicensees and Service Providers to perform) all of its Manufacturing activities in a good scientific manner and in compliance with the terms of this Agreement and all Applicable Laws.

ARTICLE 6
PAYMENTS

6.1. Upfront Payment. Licensee shall pay Sanofi Kymab an upfront payment of Three Million Dollars ($3,000,000.00) (the "**Upfront Payment**"), within ten (10) Business Days of receipt of Sanofi Kymab's invoice therefore, which invoice shall be dated no earlier than the Effective Date. The Upfront Payment is not refundable or creditable against any other payments due hereunder.

6.2. Milestones.

6.2.1. Development and Regulatory Milestones. Licensee shall notify Sanofi Kymab of achievement of each of the development and regulatory milestone events described in the table below (the "**Development and Regulatory Milestone Events**") within thirty (30) calendar days of achievement thereof by Licensee, its Affiliate or Sublicensee. Licensee shall pay Sanofi Kymab the following non-refundable, non-creditable development and regulatory milestone payments described in the table below for the applicable Development and Regulatory Milestone Events ("**Development and Regulatory Milestone Payments**") within thirty (30) calendar days after receipt of invoice therefor from Sanofi Kymab, which invoice Sanofi Kymab shall provide to Licensee following Sanofi Kymab's receipt of notice from Licensee of the achievement of the applicable Development and Regulatory Milestone Event in accordance with the preceding sentence. Each Development & Regulatory Milestones Payment shall be payable on an Indication-by-Indication basis for each of the first four Indications developed by Licensee, its Affiliates or Sublicensees, with respect to any Licensed Product to achieve the corresponding Development & Regulatory Milestones Event; provided that in respect of each Licensed Product, (i) for the first such Indication the applicable payment shall be the amount set forth below, (ii) for the second Indication the applicable payment shall be 50% of the amount set forth below, (iii) for the third Indication the applicable payment shall be 25% of the amount set forth below; and (iv) for the fourth Indication the applicable payment shall be 10% of the amount set forth below:

	Development and Regulatory Milestone Events	Development and Regulatory Milestone Payments
1	[***]	$[***]
2	[***]	$[***]
3	[***]	$[***]
4	[***]	$[***]
5	[***]	$[***]
6	[***]	$[***]

In the event that Licensee, its Affiliate or Sublicensee, as applicable, combines a Phase 1 Clinical Study and a Phase 2 Clinical Study into a Phase 1/2 Clinical Study, then the Development Milestone Payments payable for the Start of a Phase 2 Clinical Study shall be payable at the Start of the Phase 2 portion of such Phase 1/2 Clinical Study.

In the event that Licensee, its Affiliate or Sublicensee, as applicable, combines a Phase 2 Clinical Study and a Phase 3 Clinical Study into a Phase 2/3 Clinical Study, and the Development Milestone Payment payable for the Start of a Phase 2 Clinical Study has not been paid, then the Development Milestone Payments payable for each of the Start of a Phase 2 Clinical Study and a Phase 3 Clinical Study shall both be payable at the Start of such Phase 2/3 Clinical Study.

Nothing in this Section 6.2.1 (Development and Regulatory Milestones) shall be construed as to limit or otherwise cap any payments owed to Sanofi Kymab under any other provision of this Agreement, including without limitation Section 6.5 (Sublicense Income; Transfer Income).

With respect to Development and Regulatory Milestone Events other than those for Market Approval in a country or region, if a latter event is achieved before an earlier event, then the Development and Regulatory Milestone Payment for the earlier Development and Regulatory Milestone Event shall become due and payable upon the achievement of the next Development and Regulatory Milestone.

6.2.2. Sales Milestones. Licensee shall notify Sanofi Kymab of achievement of each Sales Milestone event described in the table below (each a "**Sales Milestone Event**") by Licensee, its Affiliate or Sublicensee within sixty (60) calendar days of the end of the Calendar Year in which such Sales Milestone Event is first achieved. Licensee shall pay Sanofi Kymab the following non-refundable, non-creditable payments (each a "**Sales Milestone Payments**"), described in the table below within thirty (30) calendar days after receipt of invoice therefor from Sanofi Kymab, which invoice Sanofi Kymab shall provide to Licensee following Sanofi Kymab's receipt of notice from Licensee of the achievement of the applicable Sales Milestone Event in accordance with the preceding sentence. Each Sales Milestone Payment below is payable one time only.

	Sales Milestone Events	Sales Milestone Payments
A	Aggregate Net Sales of all Licensed Products in the Territory in a Calendar Year exceed [***]	[***]
B	Aggregate Net Sales of all Licensed Products in the Territory in a Calendar Year exceed [***]	[***]
C	Aggregate Net Sales of all Licensed Products in the Territory in a Calendar Year exceed [***]	[***]

6.2.3. Determination that Milestone Events Have Occurred. In the event that Licensee has not provided Sanofi Kymab notice of achievement of a particular Milestone Event as provided in Section 6.2.1 (Development and Regulatory Milestones) or Section 6.2.2 (Sales Milestones), and Sanofi Kymab believes that any such Milestone Event has been achieved then Sanofi Kymab shall so notify Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such Milestone Event has been achieved. Any dispute under this Section 6.2 (Milestones) regarding whether or not a Milestone Event has been achieved shall be subject to resolution in accordance with Section 13.6 (Dispute Resolution).

6.3. Royalties.

6.3.1. Royalty Rates. Licensee shall pay Sanofi Kymab the applicable royalty set forth below on Net Sales of Licensed Products in the Territory for each Calendar Year (or partial Calendar Year) during the Royalty Term as follows:

That portion of Net Sales of all Licensed Products in the Territory in a Calendar Year that is:	Royalty rate
Less than $[***]	[***]
Equal to or greater than $[***] but less than $[***]	[***]
Equal to or greater than $[***]	[***]

6.3.2. Adjustments to Royalties.

(i) **Absence of Valid Claim**. If during the Royalty Term a Licensed Product is sold in any country and such Licensed Product is not covered by a Valid Claim of a Licensed Product Patent or Derived Patent in such country, then the royalty rate on such Licensed Product in such country, shall be reduced by [***] of the rate specified in the table in Section 6.3.1 (Royalty Rates).

(ii) **Third Party License.** On a Licensed Product-by-Licensed Product, Indication-by-Indication and country-by-country basis, (a) if Licensee must obtain a license from

any Third Party to a Patent Controlled by such Third Party (a "**Third Party License**") in order to Exploit such Licensed Product in such Indication in such country, then the royalty payment that would otherwise be due to Sanofi Kymab in any Calendar Quarter shall be reduced, on a Calendar Quarter-by-Calendar Quarter basis, by [***] of any royalty payment payable to such Third Party in such Calendar Quarter in consideration for such Third Party License.

6.3.3. Limitation on Royalty Adjustments. Notwithstanding any provision to the contrary set forth in this Agreement, the royalty payments that would otherwise be due to Sanofi Kymab pursuant to Section 6.3.1 (Royalty Rates) with respect to a particular Calendar Quarter shall not be reduced by more than [***] by operation of Section 6.3.2(i) (Adjustments to Royalties).

6.4. Payment Dates and Reports. Royalty payments shall be made by Licensee within [***] calendar days after the end of each Calendar Quarter commencing with the Calendar Quarter in which the first day of the first Royalty Term for the first Licensed Product occurs. Licensee shall also provide to Sanofi Kymab, at the same time each such payment is made, a report showing: (a) the Invoiced Sales and Net Sales of the Licensed Products by country in the Territory; (b) the calculation for any deductions from Invoiced Sales to Net Sales; (c) applicable royalty rates for the Licensed Products; (c) the exchange rates used in calculating any of the foregoing; (d) a calculation of the amount of royalty due to Sanofi Kymab, and (e) date of First Commercial Sale of each Licensed Product in each country within the Territory where Market Approval has been obtained.

6.5. Sublicense Income; Transfer Income.

6.5.1. Sublicense Income. Licensee shall pay Sanofi Kymab the following percentage of all Sublicense Income received by Licensee as consideration for the grant of a sublicense of its rights under Section 2.1 (Grants) with respect to each Indication of any Licensed Product within thirty (30) calendar days after such Sublicense Income is received by Licensee: (a) [***] for any sublicense granted prior to [***]; (b) [***] for any sublicense granted after [***]; (c) [***] for any sublicense granted after [***]; and (d) [***] for any sublicense granted after [***].

6.5.2. Transfer Income. Licensee shall pay Sanofi Kymab the following percentage of all Transfer Income received by Licensee as consideration for the assignment of its rights under Section 2.1 (Grants) within thirty (30) calendar days after such Transfer Income is received by Licensee: (a) [***] for any assignment executed prior to [***]; (b) [***] for any assignment executed after [***]; (c) [***] for any assignment executed after [***]; (d) [***] for any assignment executed after [***], and (e) [***] for any assignment executed after [***].

6.6. Priority Review Voucher. [***].

6.7. Mode of Payment; Current Conversion TC "6.5 Mode of Payment; Currency Conversion" \f C \l "2" **.**

(i) All payments to Sanofi Kymab under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as Sanofi Kymab may from time to time designate on notice to Licensee.

(ii) If any currency conversion shall be required in connection with any payment hereunder, then such conversion shall be made by using the arithmetic mean of the exchange rates for the purchase of Dollars as published in *The Wall Street Journal*, Eastern Edition, on the last Business Day of each month in the Calendar Quarter to which such payments relate.

6.8. Taxes TC "6.6 Taxes" \f C \l "2" . The upfront payment, milestone payments and other amounts payable by Licensee to Sanofi Kymab pursuant to this Agreement ("**Payments**") shall not be reduced on account of any taxes unless required by Applicable Law. Sanofi Kymab alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Licensee shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Sanofi Kymab is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Licensee of its obligation to withhold tax, and Licensee shall apply the reduced rate of withholding, or dispense with withholding, as the case may be; provided that Licensee has received evidence, in a form reasonably satisfactory to Licensee, of Sanofi Kymab's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] calendar days prior to the time that the Payments are due. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to Sanofi Kymab the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Sanofi Kymab proof of such payment within ten days following such payment. Licensee shall be responsible for any sales or other similar tax that Sanofi Kymab may be required to collect with respect to the Payments.

6.9. Interest on Late Payments. If any undisputed Payment due to Sanofi Kymab under this Agreement is not paid when due, then Licensee shall pay interest thereon and on any unpaid accrued interest (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of three hundred (300) basis points above the rate utilized by the United States Federal Reserve Bank, such interest to run from the date upon which payment of such amount became due until payment thereof in full together with such accrued interest.

6.10. Financial Records. Licensee shall, and shall cause its Affiliates and Sublicensees, to (a) keep complete and accurate books and records pertaining to the sale, delivery and use of the Licensed Products, including books and records of Invoiced Sales (including any deductions therefrom) and Net Sales of the Licensed Products in the Territory and (b) complete unredacted copies of all Sublicense Agreements and any Third Party License. Licensee shall, and shall cause its Affiliates and Sublicensees to, retain such books and records, until the later of (3) three years after the end of the period to which such books and records pertain and the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

6.11. Audit TC "6.9 Audit" \f C \l "2" **.** At the request of Sanofi Kymab, Licensee shall, and shall cause its Affiliates and Sublicensees to, permit an independent certified public accountant retained by Sanofi Kymab, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 6.10 (Financial Records). Licensee will provide to such independent certified public accountant complete unredacted copies of each Sublicense

Agreement and Third Party License executed by Licensee, its Affiliate or Sublicensee in connection with any audit conducted under this Section 6.11 (Audit); provided that such copies remain with the independent certified public accountants for the sole purpose of such audits. Such audits may not (a) be conducted for any Calendar Quarter more than three years after the end of such Calendar Quarter, (b) be conducted more than once in any 12-month period (unless a previous audit during such 12-month period revealed an underpayment of more than 5% with respect to such period or Licensee restates or revises such books and records for such 12-month period) or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of any audit shall be borne by Sanofi Kymab, unless the audit reveals an underpayment of more than 5% from the reported amounts, in which case Licensee shall reimburse Sanofi Kymab's costs for the audit, and pay Sanofi Kymab's invoice therefore within thirty (30) calendar days. Unless disputed pursuant to Section 6.12 (Audit Dispute), if such audit concludes that additional payments are owed for the audited period, Licensee shall pay the additional amounts, with interest from the date originally due, within thirty (30) calendar days after the date on which Sanofi Kymab delivers the auditor's findings to Licensee.

6.12. Audit Dispute TC "6.10 Audit Dispute" \f C \l "2" **.** In the event of a dispute over the results of any audit conducted pursuant to Section 6.11 (Audit), Sanofi Kymab and Licensee shall work in good faith to resolve such dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] calendar days, the dispute shall be submitted for arbitration to a certified public accounting firm selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Accountant**") or failing such agreement, as the Chairman of the International Chamber of Commerce (or such other body as the Parties may mutually agree), may nominate. The decision of the Accountant shall be final and the costs of such arbitration, as well as the initial audit, shall be borne between the Parties in such manner as the Accountant shall determine. Not later than [***] calendar days after such decision and in accordance with such decision, Licensee shall pay the additional royalties, with interest from the date originally due.

6.13. Confidentiality TC "6.11 Confidentiality" \f C \l "2" Sanofi Kymab shall treat all information provided by Licensee under this Article 6 (Payments) in accordance with Article 9 (Confidentiality and Non-Disclosure) and Sanofi Kymab shall cause any accountant retained by Sanofi Kymab pursuant to Section 6.11 (Audit) or the Accountant, as applicable, to enter into a confidentiality agreement that includes an obligation to retain all such financial information it receives from the Parties in confidence.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1. Ownership of Arising Know-How. As between the Parties, Licensee shall own and retain all right, title and interest in and to any and all Know-How that arises from, or is created or otherwise made by or on behalf of Licensee or its Affiliates or Sublicensees in performance of the exercise of the rights and licenses granted to Licensee pursuant to Section 2.1 (Grants). Licensee shall have the sole right to prepare, file, prosecute, maintain, enforce and defend (including with respect to related interference, re-issuance, re-examination and opposition proceedings) any Patent claiming such arising Know-How, at its own cost and expense.

7.2. Prosecution and Maintenance of Patents.

7.2.1. **Licensed Product Patents**. Licensee shall have the first right to prepare, file, prosecute, maintain, enforce and defend (including with respect to related interference, re-issuance, re-examination and opposition proceedings) the Licensed Product Patents in the Territory, at its sole cost and expense, using outside counsel reasonably acceptable to Sanofi Kymab, and in any case, with reasonable care and skill; provided that (i) [***]; and (ii) [***]. If [***] plans to abandon any Licensed Product Patent in the Territory, Licensee shall notify Sanofi Kymab in writing at least [***] in advance of the due date of any payment or other action that is required to prosecute and maintain such Licensed Product Patent and all licenses under such Licensed Product Patent [***] and [***] shall thereafter have the sole right to prosecute, maintain, enforce and defend such Licensed Product Patent. [***].

7.2.2. **Licensed Platform Patents; Licensed Anemia Patents.** As between the Parties, Sanofi Kymab shall have the sole right, but not the obligation, to prepare, file, prosecute, maintain, enforce and defend (including with respect to related interference, re-issuance, re-examination and opposition proceedings) any Licensed Platform Patents in the Territory, at its sole cost and expense. As between the Parties, Sanofi Kymab shall have the sole right, but not the obligation, to prepare, file, prosecute, maintain, enforce and defend (including with respect to related interference, re-issuance, re-examination and opposition proceedings) any Licensed Anemia Patents in the Territory, at its sole cost and expense.

7.2.3. **Derived Patents.** Licensee shall have the sole right to prepare, file, prosecute, maintain, enforce and defend (including with respect to related interference, re-issuance, re-examination and opposition proceedings) any Derived Patent in the Territory, at its sole cost and expense. Licensee shall notify Sanofi Kymab of any Derived Patents filed within thirty (30) calendar days of filing. To the extent necessary, Sanofi Kymab shall cooperate with Licensee to file Derived Patents, including by providing evidence of assignment of rights from Sanofi Kymab's inventor employees. Licensee shall, where practicable, request such evidence in writing at least [***] days prior to the planned filling date of such Derived Patent.

7.2.4. **Patent Term Extension and Supplementary Protection Certificate.** Licensee shall have the sole right, but not the obligation, to apply for any patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, with respect to the Licensed Product Patents in any country in the Territory at Licensee's cost in Licensee's name, or if required by applicable laws or regulations, in Sanofi Kymab's or its Affiliate's name as applicable, and Sanofi Kymab shall execute such authorizations and other documents and take such other actions as may be reasonably requested to obtain such patent term extensions. Licensee shall reimburse Sanofi Kymab for its costs and expenses associated therewith within thirty (30) calendar days of receipt of Sanofi Kymab's invoice therefor. Notwithstanding the foregoing, in the event that Sanofi Kymab wishes Licensee to apply for a patent term extension or supplementary protection certificate with respect to any Licensed Product Patents in any country which Licensee does not itself intend to file, then Licensee will consider Sanofi Kymab's request in good faith, and if Licensee agrees to Sanofi Kymab's request, Sanofi Kymab shall reimburse Licensee for its costs and expenses associated therewith within thirty (30) calendar days of receipt of Licensee's invoice therefore. Sanofi Kymab shall have the sole right, but not the obligation, to apply for any patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, with respect to the Licensed Platform Patents and Licensed Anemia Patents and in connection with any pharmaceutical product that is not a Licensed Product.

7.3. Enforcement of Patents.

7.3.1. Notice. In the event either Party becomes aware of (a) any suspected infringement of any Licensed Product Patents or (b) any certification filed under the Hatch-Waxman Act claiming that any Licensed Product Patents are invalid or unenforceable or claiming that any Licensed Product Patents would not be infringed by the making, use, offer for sale, sale or import of a product for which an application under the Hatch-Waxman Act is filed, or any equivalent or similar certification or notice in any other jurisdiction in the Territory (each of clauses (a) and (b), an "**Infringement**"), such Party shall promptly notify the other Party and provide it with the details of such Infringement of which it is aware (each, an "**Infringement Notice**"); *provided* that each Party shall give the other Party an Infringement Notice not later than three (3) Business Days after it becomes aware of any Infringement described in clause (b) above.

7.3.2. Licensed Product Patents in the Territory. Licensee shall have the first right, but not the obligation, through counsel of its choosing, to initiate an infringement action with respect to any Infringement of any Licensed Product Patents at its sole cost and expense. Licensee may, subject to Section 2.3 (Sublicenses), grant the infringing Third Party a sublicense as Licensee deems appropriate. If Licensee does not initiate such an infringement action within [***] calendar days (or twenty-five (25) calendar days in the case of any Infringement described in clause (b) of the definition thereof) of learning of such Infringement, or earlier notifies Sanofi Kymab in writing of its intent not to so initiate an action, and Licensee has not granted such infringing Third Party rights and licenses to continue its otherwise infringing activities, then Sanofi Kymab and Licensee shall discuss such matter in good faith to determine a course of action. If the Parties are unable to agree on a course of action within thirty (30) calendar days, then Sanofi Kymab shall have the right, but not the obligation, to bring such an action. [***].

7.3.3. Settlement. The Party that controls the prosecution of a given Infringement claim pursuant to Section 7.3.2 (Licensed Product Patents in the Territory) also shall have the right to control settlement of such claim; *provided* that no settlement shall be entered into without the prior consent of the other Party if such settlement would adversely affect or diminish the rights or benefits of the other Party under this Agreement, or impose any new obligations or adversely affect any obligations of the other Party under this Agreement.

7.3.4. Cooperation. In the event a Party is entitled to and brings an infringement action in accordance with this Section 7.3 (Enforcement of Patents), the non-controlling Party shall provide reasonable assistance and cooperation, at the controlling Party's cost, including being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. If a Party pursues an action against such alleged Infringement, then it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to preclude such infringement.

7.3.5. Costs and Recovery. Any damages or other amounts collected from any such Infringement action shall be first allocated to reimburse the Parties for their respective costs and expenses in making such recovery (which amounts shall be allocated *pro rata* if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall (a) before the First Commercial Sale of the considered Licensed Product, be shared [***] for Sanofi Kymab and [***] for Licensee, or (b) after the First Commercial Sale of the considered Licensed Product, be included in the Net Sales calculation for such Licensed Product.

7.4. Infringement Claims by Third Parties.

7.4.1. Defense of Third Party Claims. If a Third Party files a claim and asserts that a Patent or other intellectual property right owned or otherwise controlled by such Third Party is infringed by the Exploitation of the Licensed Products in the Field in the Territory, the Party first made aware of such a claim shall promptly provide the other Party written notice of such claim along with the related facts in reasonable detail. Licensee shall have the first right, but not the obligation, to control the defense of such claim. If Licensee fails to assume control of the defense of such claim within [***] calendar days after receiving notice thereof from, or giving notice thereof to, Sanofi Kymab pursuant to the first sentence of this Section 7.4.1 (Defense of Third Party Claims), then Sanofi Kymab shall have the right, but not the obligation, to defend against any such claim that is filed against Sanofi Kymab (but not Licensee). Notwithstanding the foregoing, the Party controlling such defense (the "**Controlling Party**") shall not be entitled to assert a claim or counterclaim against such Third Party based on the Patents or other intellectual property rights owned or otherwise controlled by the other Party (the "**Non-Controlling Party**") without the prior written consent of the Non-Controlling Party, such consent not to be unreasonably conditioned, withheld or delayed. The Non-Controlling Party shall cooperate with the Controlling Party, at the Controlling Party's reasonable request and expense, in any such defense and shall have the right, at its own expense, to be represented separately by counsel of its own choice in any such proceeding.

7.4.2. Settlement of Third Party Claims. The Controlling Party with respect to a particular claim pursuant to Section 7.4.1 (Defense of Third Party Claims) also shall have the right to control settlement of such claim; *provided* that (a) no settlement shall be entered into without the prior written consent of the Non-Controlling Party if such settlement would adversely affect or diminish the rights and benefits of the Non-Controlling Party under this Agreement, or impose any new obligations or adversely affect any obligations of the Non-Controlling Party under this Agreement, and (b) the Controlling Party shall not be entitled to settle any such claim by granting a license or covenant not to sue under or with respect to the Patents or other intellectual property rights owned or otherwise controlled by the Non-Controlling Party without the prior written consent of the Non-Controlling Party, such consent not to be unreasonably conditioned, withheld or delayed.

7.4.3. Allocation of Costs. All costs and expenses relating to any defense, settlement and judgments in actions commenced pursuant to this Section 7.4 (Infringement Claims by Third Parties) shall be borne by the Party that incurs such cost.

7.5. Invalidity or Unenforceability Defenses or Actions.

7.5.1. Third Party Defense or Counterclaim.

(i) If a Third Party asserts, as a defense or as a counterclaim in any infringement action filed under Section 7.3 (Enforcement of Patents) or claim or counterclaim asserted under Section 7.4 (Infringement Claims by Third Parties), or in a declaratory judgment action or similar action or claim filed by such Third Party, that any Licensed Product Patent is invalid or unenforceable, then the Party pursuing such infringement action, or the Party first obtaining knowledge of such declaratory judgment action, as the case may be, shall promptly give written notice to the other Party.

(ii) Licensee shall have the first right, but not the obligation, through counsel of its choosing, at its sole cost and expense, to defend against such action. If Licensee fails to exercise its first right to control of the defense of such action (as it considers such Licensed Product Patent to no longer be of strategic value to it, its Affiliates or Sublicensees) within ninety (90) calendar days after receiving notice thereof from, or giving notice thereof to, then Sanofi Kymab shall have the right to defend such action, through counsel of its choosing, at its sole cost and expense, to defend against such action, and in such event under such Licensed Product Patents granted in Section 2.1 (Grants) shall terminate unless Licensee pays Sanofi Kymab [***] of the external costs incurred by Sanofi Kymab in defending such action.

7.5.2. Assistance. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in Section 7.5.1 (Third Party Defense or Counterclaim), including by providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that neither Party shall be required to disclose legally privileged information unless and until procedures reasonably acceptable to such disclosing Party are in place to protect such privilege. In connection with any such defense or claim or counterclaim, the Controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim or counterclaim. In connection with the activities set forth in Section 7.5.1 (Third Party Defense or Counterclaim), each Party shall consult with the other as to the strategy for the defense of the Licensed Product Patents.

7.6. Third Party Licenses. If Licensee obtains a license from any Third Party in order to Exploit a Licensed Product in the Field in the Territory, as between the Parties, Licensee shall be solely responsible for all license fees, milestones, royalties or other such payments due to such Third Party; provided however that Licensee may deduct from the payments it otherwise must pay to Sanofi Kymab under Section 6.3 (Royalties) the payments made to such Third Party if the conditions of Section 6.3.2(ii) (Third Party Licenses) are met.

7.7. Product Trademarks.

7.7.1. Selection and Ownership of Product Trademarks. Licensee shall have the right to select and own the Product Trademarks to be used with respect to the Exploitation of the Licensed Products in the Field in the Territory, at its costs and expense.

7.7.2. Maintenance and Prosecution of Product Trademarks. Licensee shall have sole control over and decision-making authority with respect to the registration, prosecution and maintenance of Product Trademarks, at its cost and expense.

7.7.3. Enforcement of Product Trademarks. Licensee shall have the sole right to take action against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory. Licensee shall bear the costs and expenses relating to any enforcement action commenced pursuant to this Section 7.7.3 (Enforcement of Product Trademarks) and any settlements and judgments with respect thereto and shall retain any damages or other amounts collected in connection therewith.

7.7.4. **Third Party Claims.** Licensee shall have the sole right to defend against any alleged, threatened or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of such Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Licensed Product in the Territory. Licensee shall bear the costs and expenses relating to any defense commenced pursuant to this Section 7.7.4 (Third Party Claims) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

ARTICLE 8
PHARMACOVIGILANCE AND SAFETY

8.1. **Global Safety Database.** tc “8.2 Global Safety Database.” \f C \l 2 Licensee shall set up, hold, and maintain (at Licensee’s sole cost and expense) the global safety database for the Licensed Products in the Territory. If required by Applicable Law, and on Sanofi Kymab’s request, Licensee shall grant Sanofi Kymab access to such global safety database for the Licensed Products or provide Sanofi Kymab with global safety data reports to comply with any such Applicable Law.

8.2. **Pharmacovigilance Agreement.** Where required by Applicable Law, the Parties shall execute a safety data exchange or other applicable pharmacovigilance agreement.

ARTICLE 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1. **Confidentiality Obligations.** At all times during the Term and for a period of [***] following termination or expiration of this Agreement, each Party shall, and shall cause its Affiliates and, in the case of Licensee as the Receiving Party its Sublicensees, and with respect to both Parties their respective officers, directors, employees and agents to, keep completely confidential (using not less than the efforts that such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort) and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or such use is reasonably necessary for the performance of its obligations or the exercise of its rights under this Agreement. “**Confidential Information**” means any confidential or proprietary information Controlled and provided by one (1) Party or its Affiliates (the “**Disclosing Party**”) to the other Party or its Affiliates (the “**Receiving Party**”) under or in connection with this Agreement, including the terms of this Agreement or any information relating to the Licensed Products, any information relating to any Exploitation of the Licensed Products in the Territory or the scientific, regulatory or business affairs or other activities of either Party, regardless of whether any of the foregoing are marked “confidential” or “proprietary” or communicated to the other Party by or on behalf of the disclosing Party in oral, written, visual, graphic or electronic form. Notwithstanding the foregoing, Confidential Information shall not include any information that:

9.1.1. is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act or omission on the part of the Receiving Party in breach of this Agreement;

9.1.2. was obtained or was already known by the Receiving Party or any of its Affiliates without obligation of confidentiality as a result of disclosure from a Third Party that neither the Receiving Party nor any of its Affiliates knew was under an obligation of confidentiality to the Disclosing Party or any of its Affiliates with respect to such information;

9.1.3. was previously or is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information; or

9.1.4. can be demonstrated by documentation or other competent evidence to have been independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

9.2. Permitted Disclosures. Each Receiving Party may disclose Confidential Information disclosed to it by the Disclosing Party to the extent that such disclosure by the Receiving Party is:

9.2.1. necessary to comply with Applicable Law including disclosure that a Party is compelled to make in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction (including prosecution or defense of litigation) if, in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance with Applicable Law; *provided* that the Receiving Party shall first have given notice, to the extent legally permitted, to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided*, *further*, that if a disclosure order is not quashed or a protective order is not obtained, then the Confidential Information disclosed in response to such court or governmental order shall be limited to the information that is legally required to be disclosed in response to such court or governmental order;

9.2.2. necessary to comply with the rules and regulations of the U.S. Securities and Exchange Commission (or any securities exchange in any jurisdiction in the Territory) applicable to a Party (each, a "**Securities Regulator**"), which disclosure is, in the reasonable opinion of the Receiving Party's counsel, necessary for compliance with the requirements of such securities exchange, and, in connection therewith, each Party acknowledges and agrees that the other Party may submit this Agreement to, or file this Agreement with, such Securities Regulators, provided that if a Party intends to submit this Agreement to, or intends to file this Agreement with, any Securities Regulator, such Party agrees to engage in a reasonable

consultation, on not less than [***], with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement or other Confidential Information related to this Agreement to be disclosed to such Securities Regulator;

9.2.3. made by the Receiving Party to a Regulatory Authority as required in connection with any filing, application or request for Market Approval;

9.2.4. made by the Receiving Party to file or prosecute Patent applications, prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement;

9.2.5. made by the Receiving Party to actual or prospective investors, acquirers, merger candidates, or, with respect to Sanofi Kymab as the Receiving Party, investors in connection with a Monetization (and to its and their respective Affiliates, representatives and financing sources); *provided* that (a) each such Third Party signs an agreement that contains obligations of confidentiality that are substantially similar to the Receiving Party's obligations hereunder (except that the obligations under such agreement may, if executed within three years of the Effective Date, terminate five years after the effective date of such agreement, and if executed after the third anniversary of the Effective Date, terminate [***] after the effective date of such agreement, provided that for clarity, if no Confidential Information of the Disclosing Party is disclosed to such Third Party, then the termination date of such agreement may be shorter), and (b) each such Third Party to whom information is disclosed shall (i) be subject to reasonable obligations of confidentiality, (ii) be informed of the confidential nature of the Confidential Information so disclosed and (ii) agree to hold such Confidential Information subject to the terms thereof.

9.3. Use of Name. Except as expressly provided in this Agreement including Section 9.4 (Press Releases), neither Party shall mention or otherwise use the name, insignia, symbol or other Trademark of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance, such approval not to be unreasonably conditioned, withheld or delayed. The restrictions imposed by this Section 9.3 (Use of Name) shall not prohibit either Party from making any disclosure (a) identifying the other Party as a counterparty to this Agreement to its investors, (b) that is required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body (*provided* that any such disclosure shall be governed by this Article 9 (Confidentiality and Non-Disclosure)) or (c) with respect to which written consent has previously been obtained. Further, the restrictions imposed on each Party under this Section 9.3 (Use of Name) are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, *provided* that any Confidential Information in such communications remains subject to this Article 9 (Confidentiality and Non-Disclosure).

9.4. Press Releases. On or after the Effective Date, Licensee may issue a press release to announce this Agreement in substantially the form attached hereto as Schedule 9.4 (Initial Press Release). Except as otherwise permitted in accordance with the preceding sentence or Section 9.2 (Permitted Disclosures), no Party shall issue any press release or other similar public communication relating to this Agreement, its subject matter or the transactions covered by it, or the activities of the Parties under or in connection with this Agreement, without the prior written approval of the other Party. If a Party wishes to issue any press release or other similar public communication relating to this Agreement, its subject matter or the transactions covered by it, or

the activities of the Parties under or in connection with this Agreement, then such Party shall provide the other Party reasonable opportunity to review and comment on any such press release or public communication at least [***] Business Days in advance thereof (to the extent permitted under Applicable Law), and further provided that the period of review and comment shall notwithstanding the foregoing be [***] Business Days during the months of August and December, and the issuing Party shall act in good faith to incorporate any comments provided by the other Party on such press release or public communication. This Section 9.4 (Press Releases) shall not apply with respect to (a) information that has been previously disclosed by any Party publicly or (b) disclosure of development, regulatory, or commercial progress by Licensee, its Affiliate or Sublicensee; provided that with respect to (b), such proposed disclosure would not conflict with Licensee's obligations under Section 9.3 (Use of Names)

9.5. Publications.

9.5.1. As between the Parties, and subject to Section 9.5.2, [***] may and shall have sole right to issue, disclose, release, or otherwise publish scientific information regarding the subject matter of this Agreement, including with respect to the Licensed Compounds. Any publication of papers regarding the Licensed Compounds made by or on behalf of [***] shall, acknowledge the contributions of [***] according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

9.5.2. [***].

9.6. Destruction of Confidential Information. Within ninety (90) days after the termination of this Agreement, or at the written request of the Disclosing Party, the Receiving Party shall promptly destroy all documentary, electronic or other tangible embodiments of the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder and any and all copies thereof, and destroy those portions of any documents that incorporate or are derived from the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder, and provide a written certification of such destruction, except that the Receiving Party may retain one (1) copy thereof, to the extent that the Receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this Agreement that may survive such expiration or termination, or for archival or compliance purposes. Notwithstanding the foregoing, the Receiving Party also shall be permitted to retain such additional copies of or any computer records or files containing the Disclosing Party's Confidential Information that have been created solely by the Receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES

10.1. Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

10.1.1. Corporate Authority. Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (c) is duly organized and validly existing

under the Applicable Law of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement. This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity.

10.1.2. Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation or bylaws of such Party in any material way and (b) do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

10.2. Representations, Warranties and Covenants of Sanofi Kymab. Sanofi Kymab represents and warrants to Licensee, as of the Effective Date:

10.2.1. Patents.

(i) Sanofi Kymab or its Affiliates own, and Sanofi Kymab Controls, the Patents set forth in Schedule 1.57 (Licensed Anemia Patents).

(ii) Sanofi Kymab or its Affiliates own, and Sanofi Kymab Controls, the Patents set forth in Schedule 1.60 (Licensed Platform Patents).

(iii) Sanofi Kymab Controls the Patents set forth in Schedule 1.62 (Licensed Product Patents) and to the knowledge of those specific Sanofi Kymab personnel having responsibility for the management of Licensed Product Patents Sanofi Kymab and its Affiliates are the sole and exclusive owners of such Patents free and clear of all liens, charges or encumbrances.

(iv) To the knowledge of Sanofi Kymab or its Affiliates' personnel having responsibility for the management of Licensed Product Patents, Schedule 1.62 (Licensed Product Patents) sets forth a complete and accurate list of the Patents that Sanofi Kymab and its Affiliates filed prior to the Effective Date which claim the Back-up Sequences and/or the KY1066 Sequence.

(v) To the knowledge of those specific Sanofi Kymab personnel having responsibility for the management of Licensed Product Patents, (a) the Licensed Product Patents have been diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, and (b) all applicable fees payable to a patent office related to Licensed Product Patents have been paid on or before the due date for such payments.

10.2.2. Licensed Know-How. Sanofi Kymab or its Affiliates Controls the Know-How set forth in Schedule 1.59 (Licensed Know-How).

10.2.3. Transferred Materials. Sanofi Kymab or its Affiliates Controls the materials set forth in Schedule 2.6 (Transferred Materials).

10.2.4. License. Sanofi Kymab has the right to grant the licenses and rights granted to Licensee hereunder on its own behalf and on behalf of its Affiliates.

10.2.5. Third Party Claims. To the knowledge of those specific Sanofi Kymab or its Affiliates' personnel having responsibility for such matters, Sanofi Kymab and its Affiliates have not received any written notice of any claim made by any Person (other than a governmental authority, e.g. a patent office such as the European Patent Office or the United States Patent and Trademark Office) against Sanofi Kymab or its Affiliates that alleges that any Licensed Product Patent is invalid or unenforceable.

10.3. Representations, Warranties and Covenants of Licensee TC "10.2 Representations, Warranties and Covenants of Opiant" \f C \l "2" **.** Neither Licensee nor any of its Affiliates has been debarred or is subject to debarment and neither Licensee nor any of its Affiliates will use in any capacity, in connection with the activities to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. Licensee shall inform Sanofi Kymab in writing promptly if it or any Person who is performing activities hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Licensee's knowledge, is threatened, relating to the debarment or conviction of Licensee or any Person performing activities hereunder.

10.4. DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTION 10.1 (MUTUAL REPRESENTATIONS AND WARRANTIES) AND 10.2 (REPRESENTATIONS, WARRANTIES AND COVENANTS OF SANOFI KYMAB), NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTY, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND SANOFI KYMAB SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE WITH RESPECT TO THE TRANSFERRED MATERIALS OR PURPOSE OR ANY WARRANTY AS TO FREEDOM TO OPERATE OR THE VALIDITY OF ANY LICENSED PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

10.5. ADDITIONAL WAIVER TC "10.4 ADDITIONAL WAIVER" \f C \l "2" LICENSEE ACKNOWLEDGES THAT THE LICENSED PATENTS, LICENSED KNOW-HOW AND TRANSFERRED MATERIALS WERE ACQUIRED THROUGH A TRANSACTION RELATED TO ASSETS UNRELATED TO THE SUBJECT MATTER OF THIS AGREEMENT, AND THEREFORE, LICENSEE AGREES THAT EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTION 10.1 (MUTUAL REPRESENTATIONS AND WARRANTIES) AND 10.2 (REPRESENTATIONS, WARRANTIES AND COVENANTS OF SANOFI KYMAB): (A) THE LICENSED PATENTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST SANOFI KYMAB FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE LICENSED PATENTS; (B) LICENSEE AGREES THAT SANOFI KYMAB WILL HAVE NO LIABILITY TO LICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENCE OR OTHER HANDLING OF THE LICENSED PATENTS; (C) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED PRODUCT PATENTS HAVE

APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF ANY LICENSED PRODUCT, AND LICENSEE ASSUMES ALL RISK AND LIABILITY THAT RESULTS FROM SUCH DETERMINATION; (D) SANOFI KYMAB MAKES NO REPRESENTATION OR WARRANTY AS TO THE COMPLETENESS OF THE LICENSED KNOW-HOW; (E) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED KNOW-HOW HAS APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF ANY LICENSED PRODUCT, AND LICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION; (F) THE TRANSFERRED MATERIALS ARE PROVIDED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST SANOFI KYMAB FOR CLAIM AS TO THE QUALITY OF FITNESS FOR A PARTICULAR PURPOSE OF THE TRANSFERRED MATERIALS; (G) LICENSEE AGREES THAT SANOFI KYMAB SHALL HAVE NO LIABILITY TO LICENSEE FOR THE USE OF THE TRANSFERRED MATERIALS, WHICH MATERIALS SHALL BE USED SOLEY FOR NON-CLINICAL PURPOSES AND LICENSEE ACKNOWLEGES THAT USE OF THE TRANSFERRED MATERIALS IN HUMANS IS EXPRESSLY PROHIBITED; (H) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE TRANSFERRED MATERIALS HAVE APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF ANY LICENSED PRODUCT, AND LICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

ARTICLE 11
INDEMNITY

11.1. Indemnification of Sanofi Kymab. Licensee shall indemnify Sanofi Kymab, its Affiliates and its and their respective directors, officers, employees and agents (collectively, "**Sanofi Kymab Indemnitees**"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (a) the breach by Licensee of any term of this Agreement, (b) the gross negligence or willful misconduct on the part of any Licensee Indemnitee, or (c) the Exploitation of any Licensed Compounds or Licensed Products by or on behalf of Licensee or any of its Affiliates; provided that, with respect to any Third Party Claim for which Licensee has an obligation to any Sanofi Kymab Indemnitee pursuant to this Section 11.1 (Indemnification of Sanofi Kymab) and Sanofi Kymab has an obligation to any Licensee Indemnitee pursuant to Section 11.2 (Indemnification of Licensee), each Party shall indemnify each of the Sanofi Kymab Indemnitees or the Licensee Indemnitees, as applicable, for its Losses to the extent of its responsibility, relative to the other Party.

11.2. Indemnification of Licensee. Sanofi Kymab shall indemnify Licensee, its Affiliates and its and their respective directors, officers, employees and agents (collectively, "**Licensee Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the breach by Sanofi Kymab of this Agreement and (b) the gross negligence or willful misconduct on the part of any Sanofi Kymab Indemnitee; *provided* that, with respect to any Third Party Claim for which Sanofi Kymab has an obligation to any Licensee Indemnitee pursuant to this Section 11.2 (Indemnification of Licensee) and Licensee has an obligation to any Sanofi

Kymab Indemnitee pursuant to Section 11.1 (Indemnification of Sanofi Kymab), each Party shall indemnify each of the Sanofi Kymab Indemnitees or the Licensee Indemnitees, as applicable, for its Losses to the extent of its responsibility, relative to the other Party.

11.3. Notice of Claim. All indemnification claims in respect of a Sanofi Kymab Indemnitee or a Licensee Indemnitee shall be made solely by Sanofi Kymab or Licensee, as applicable (each of Sanofi Kymab or Licensee in such capacity, the "**Indemnified Party**" and the Party having the indemnification obligation under this Agreement, the "**Indemnifying Party**"). The Indemnified Party shall give the Indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 11.1 (Indemnification of Sanofi Kymab) or Section 11.2 (Indemnification of Licensee), but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice other than in the event such delay materially prejudices the Indemnifying Party's ability to defend the applicable claim. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

11.4. Control of Defense.

11.4.1. Control of Defense. The Indemnifying Party shall assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against a Sanofi Kymab Indemnitee's or a Licensee Indemnitee's, as applicable, claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, in connection with the Third Party Claim. If the Indemnifying Party assumes the defense of a Third Party Claim, except as provided in Section 11.4.2 (Right to Participate in Defense), the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, in connection with the analysis, defense or settlement of such Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless a Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, from and against a Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) incurred by the Indemnifying Party in its defense of such Third Party Claim.

11.4.2. Right to Participate in Defense. Without limiting Section 11.4.1 (Control of Defense), any Indemnified Party shall be entitled to participate in, but not control, the defense of a Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment of counsel shall be at the Indemnified Party's own expense unless (a) the

employment of counsel thereof has been specifically authorized by the Indemnifying Party in writing, (b) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 11.4.1 (Control of Defense) (in which case the Indemnified Party shall control the defense) or (c) the interests of the Indemnified Party and any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, on the one hand, and the Indemnifying Party, on the other hand, with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of all such Persons under Applicable Law, ethical rules or equitable principles.

11.4.3. Settlement. With respect to any Third Party Claims relating solely to the payment of money damages in connection with a Third Party Claim that shall not result in any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, becoming subject to injunctive or other relief or otherwise adversely affecting the business of any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify such Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Third Party Claims not described in the preceding sentence, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.4.1 (Control of Defense), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim, *provided* that it obtains the prior written consent of the Indemnified Party (such consent not to be unreasonably conditioned, withheld or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by a Sanofi Kymab Indemnitee or a Licensee Indemnitee that is reached without the prior written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall not, and the Indemnified Party shall ensure that each Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, does not, admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably conditioned, withheld or delayed.

11.4.4. Cooperation. The Indemnified Party shall, and shall cause each Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, to cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party and any Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable, of, records and information that are reasonably relevant to such Third Party Claim, and making all Sanofi Kymab Indemnitees or Licensee Indemnitees, as applicable, and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder; *provided* that neither Party shall be required to disclose legally privileged information unless and until procedures reasonably acceptable to such Party are in place to protect such privilege, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable costs and expenses in connection therewith.

11.4.5. Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim (such as providing witnesses for such Third Party Claim) shall be

reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest any Sanofi Kymab Indemnitee's or Licensee Indemnitee's, as applicable, right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify a Sanofi Kymab Indemnitee or Licensee Indemnitee, as applicable.

11.5. Limitation on Damages and Liability. EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES (OR, IN THE CASE OF LICENSEE, ITS SUBCONTRACTORS OR SUBLICENSEES), OR WITH RESPECT TO A BREACH OF ARTICLE 9 (CONFIDENTIALITY AND NON-DISCLOSURE), NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR LOST PROFITS OR LOST REVENUE, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

11.6. Insurance. Licensee shall, and shall cause its Affiliates to, have and maintain such type and amounts of liability insurance covering the Exploitation of the Licensed Products as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and shall upon request provide Sanofi Kymab with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto. Maintenance of such insurance coverage shall not relieve Licensee of any responsibility under this Agreement for damages in excess of insurance limits or otherwise.

ARTICLE 12
TERM AND TERMINATION

12.1. Term. This Agreement shall commence on the Effective Date and shall, unless earlier terminated in accordance with this Article 12 (Term and Termination), continue (a) with respect to each Licensed Product in each country in the Territory, until the expiration of the Royalty Term for such Licensed Product in such country and (b) with respect to this Agreement in its entirety, until the expiration of the Royalty Term for the last Licensed Product for which there has been a First Commercial Sale in the Territory (such period, the "**Term**"). Upon expiry of the Royalty Term in any country, Licensee's license with respect to the applicable Licensed Product in such country shall become fully paid-up, perpetual and irrevocable.

12.2. Termination for Convenience. Licensee may terminate this Agreement, for any reason or no reason, upon [***] prior notice to Sanofi Kymab.

12.3. Termination of this Agreement for Material Breach TC "12.2 Termination of this Agreement for Material Breach" \f C \l "2" **.** In the event that a Party materially breaches this Agreement (such Party, the "**Breaching Party**"), the other Party (the "**Complaining Party**") may in addition to any other right and remedy it may have, terminate this Agreement, upon [***] prior written notice (the "**Termination Notice Period**") to the Breaching Party, which notice shall specify the material breach and its claim of right to terminate; provided that the termination shall not become effective at the end of the Termination Notice Period if the Breaching Party cures the material breach complained of during the Termination Notice Period , except in the case of a payment breach, as to which the Breaching Party shall have only a [***]

cure period; and further provided however that the Complaining Party will not unreasonably withhold its consent to extend the Termination Notice Period if so requested in writing by the Breaching Party, for so long as the Executive Officers of each Party are engaged in discussions in accordance with Section 13.6 (Dispute Resolution).

12.4. Termination by Sanofi Kymab for Patent Challenge TC "12.3 Termination by Sanofi" \f C \l "2" **.**

12.4.1. In the event that Licensee or any of its Affiliates anywhere in the Territory, institutes, prosecutes or otherwise participates in (or in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity before any court or administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy or for an enjoinment, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging in such proceeding that any claim in a Licensed Product Patent or a Licensed Platform Patent or a Licensed Anemia Patent (a) is invalid, unenforceable or otherwise not patentable or (b) would not be infringed by Licensee's activities contemplated by this Agreement absent the rights and licenses granted hereunder Sanofi Kymab may terminate this Agreement immediately upon written notice to Licensee.

12.4.2. In the event that Sanofi Kymab or its Affiliate initiates a claim, demand, action or cause of action against Licensee or its Affiliates under this Agreement, including without limitation, pursuant to Section 6.12 (Audit Dispute) or Section 12.3 (Termination of this Agreement for Material Breach), Licensee and its Affiliates may notwithstanding Section 12.4.1, assert as a defence, counterclaim or other defensive countermeasure in such proceeding that a Licensed Product Patent or a Licensed Platform Patent or a Licensed Anemia Patent would not be infringed by Licensee's activities contemplated by this Agreement absent the rights and licenses granted hereunder, and in such case, Sanofi Kymab shall have no right to terminate this Agreement under this Section 12.4.

12.5. Termination Upon Insolvency TC "12.4 Termination Upon Insolvency" \f C \l "2" . San Kymab may terminate this Agreement if, at any time, Licensee (a) files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding that is not dismissed within sixty (60) calendar days after the filing thereof, (d) proposes or is a party to any dissolution or liquidation, or (e) makes an assignment for the benefit of its creditors.

12.6. Rights in Bankruptcy TC "12.5 Rights in Bankruptcy" \f C \l "2" **.** All rights and licenses granted under or pursuant to this Agreement by Sanofi Kymab are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Licensee, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Sanofi Kymab under the U.S. Bankruptcy Code, Licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Licensee's possession, shall be promptly delivered

to it (a) upon any such commencement of a bankruptcy proceeding upon Licensee's written request therefor, unless Sanofi Kymab subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of Sanofi Kymab upon written request therefor by Licensee. To the extent available in countries other than the U.S., Applicable Law similar to Section 365(n) of the U.S. Bankruptcy Code shall be applied so as to treat this Agreement as an executory contract.

12.7. Consequences of Termination TC "12.6 Consequences of Termination" \f C \l "2" In the event of a termination of this Agreement in its entirety:

(i) all rights and licenses granted by Sanofi Kymab hereunder (including under any Sublicense Agreement) shall immediately terminate and all rights granted to Licensee, its Affiliates and Sublicensees shall revert to Sanofi Kymab;

(ii) if Sanofi Kymab has an interest in assuming the Exploitation of any Licensed Compound and/or Licensed Product in the Field in the Territory, the Parties shall negotiate in good faith: (A) a license or other transaction to provide Sanofi Kymab rights to the Patents, Know-How, materials and other properties Controlled by Licensee and/or its Affiliates which Sanofi Kymab may require to so Exploit such Licensed Compound and/or Licensed Product in the Field in the Territory; and (B) where permitted by Applicable Law, the assignment to Sanofi Kymab all of its right, title and interest in and to, and transfer possession to Sanofi Kymab of, all Regulatory Documentation (including, for clarity, Regulatory Approvals) then in its name applicable to any Licensed Product in the Territory; provided that neither Party will be obligated to enter into any such agreement and may do so in its sole discretion; and

(iii) to the extent that any Sublicensee has complied with its Sublicense Agreement and agrees to assume all obligations of Licensee, Sanofi Kymab may, at its election, enter into a direct license agreement with such Sublicensee; provided however that if Sanofi Kymab had granted its consent to Licensee's entering into a Sublicense Agreement with a particular Sublicensee in accordance with Section 2.3 (Sublicenses) then Sanofi Kymab will, if requested by such Sublicensee, enter into a direct license agreement with such Sublicensee.

12.8. Accrued Rights; Surviving Obligations.

12.8.1. Accrued Rights. Termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

12.8.2. Survival. The following Sections and Articles shall survive the termination or expiration of this Agreement for any reason: Section 6.6 (Priority Review Voucher); Section 6.11 (Audit); Section 6.12 (Audit Dispute); Section 6.13 (Confidentiality) solely with regard to the auditable period up to the effective date of termination; Section 7.4 (Infringement Claims by Third Parties) solely with respect to any enforcement actions ongoing as of the effective date of termination; Section 12.1 (Term) solely with respect to the final sentence thereof provided that Licensee's royalty and other payment obligations have been fulfilled as of the date of expiration or termination of this Agreement; Section 12.7 (Consequences of Termination); and this Section 12.8 (Accrued Rights; Surviving Obligations); Article 1 (Definitions) to the extent necessary to give effect to surviving provisions; Article 6 (Payments) with regard to any payment obligations which accrued prior to termination or expiration and also with regard to any

post-termination or post-expiration payments; Article 9 (Confidentiality and Non-Disclosure) for the period prescribed in Section 9.1 (Confidentiality Obligations); Article 11 (Indemnity), provided that Section 11.6 (Insurance) shall survive only with respect to insurable events which occurred during the period prior to termination or expiration; and Article 13 (Miscellaneous) to the extent necessary to give effect to surviving provisions.

ARTICLE 13
MISCELLANEOUS

13.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (each, a "**Force Majeure Event**"). The non-performing Party shall notify the other Party of a Force Majeure Event within 15 days after the occurrence of such Force Majeure Event by giving written notice to the other Party stating the nature of such Force Majeure Event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. In the event that such suspension of performance lasts for more than 180 days and in the absence of such Force Majeure Event such suspension of performance would be a material breach of this Agreement, such other Party shall have the right to terminate this Agreement pursuant to Section 12.2 (Termination of this Agreement for Material Breach).

13.2. Alliance Managers. Within thirty (30) days after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development and commercialization issues, to act as its alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as the primary contact points between the Parties for the purpose of Sanofi Kymab facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

13.3. Export Control TC "13.3 Export Control" \f C \l "2" **.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

13.4. Assignment; Change of Control. Except as provided in this Section 13.4 (Assignment; Change of Control), this Agreement may not be assigned or transferred, whether by operation of law or otherwise, nor may any right or obligation hereunder be assigned or transferred,

by either Party without the prior written consent of the other Party; *provided*, *however*, that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder in whole or in part: (a) to its successor in interest in the transfer or sale of all or substantially all of its assets or business related to the subject matter of this Agreement; or (b) to its successor in interest in a merger or consolidation (or similar transaction) of the assigning Party. In addition, Sanofi Kymab will have the right, without the consent of Licensee, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, and (ii) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates. Any successor of Licensee, or any assignee or delegee of all of Licensee's rights under this Agreement that has also assumed all of Licensee's obligations hereunder in writing will, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for Licensee, whereupon Licensee will cease to be a party to this Agreement and will cease to have any rights or obligations under the Agreement; *provided*, *however*, in the case of an assignment by Licensee to its Affiliate, Licensee will be jointly and severally liable with such Affiliate assignee under this Agreement. Any attempted assignment not in accordance with this Section 13.4 (Assignment; Change of Control) will be void. Further, Sanofi Kymab may assign its right to obtain payment(s) hereunder upon written notice to Licensee. All validly assigned and delegated rights and obligations of a Party hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of such Party, as the case may be.

13.5. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision shall be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights or obligations of either Party will not be materially and adversely affected, all other provisions of this Agreement shall remain in full force and effect, and the Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal, or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

13.6. Dispute Resolution TC "13.6 Dispute Resolution" \f C \l "2" . If a dispute arises between the Parties in connection with the interpretation, validity or performance of this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), then either Party shall have the right to refer such dispute to the Executive Officers for attempted resolution by good faith negotiations during a period of [***] Business Days. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. If such Executive Officers are unable to resolve such Dispute within such [***] Business Day period, either Party shall have the right to initiate litigation and seek such remedies as may be available to such Party. Notwithstanding this Section 13.6 (Dispute Resolution), each Party shall be entitled to initiate litigation without having first referred a dispute to the Executive Officers if litigation is necessary to prevent irreparable harm to that Party.

13.7. Governing Law, Jurisdiction, and Venue.

13.7.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement

to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

13.7.2. Jurisdiction. Subject to Section 13.7 (Governing Law, Jurisdiction and, Venue) and Section 13.11 (Equitable Relief), the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

13.7.3. Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

13.8. Notices.

13.8.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.8.2 (Address for Notice) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 13.8 (Notices). Such notice shall be deemed to have been given as of the date delivered by such internationally recognized overnight delivery service. This Section 13.8 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement. Telephone numbers are provided solely to facilitate delivery by courier.

13.8.2. Address for Notice.

If to Licensee, to:

c/o Rallybio IPE, LLC
234 Church Street, Suite 1020
New Haven, CT 06510

Attention: General Counsel
Email: legal@rallybio.com (which does not constitute notice)

If to Sanofi Kymab, to:

c/o Sanofi
82, avenue Raspail
94250 Gentilly, France

Attention: Head of Out-Licensing Management

Global Alliance Management
Telephone: [***]
Email: alliance.management@sanofi.com (which does not constitute notice)

13.9. Entire Agreement; Amendments TC "13.9 Entire Agreement; Amendments" \f C \l "2" . This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. No amendment of this Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.10. English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.11. Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in Article 9 (Confidentiality and Non-Disclosure) are reasonable and necessary to protect the legitimate interests of each of them and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of Article 9 (Confidentiality and Non-Disclosure) may result in irreparable injury to the other Party for which there may be no adequate remedy at law. In the event of such a breach or threatened breach of any provision of this Agreement, the aggrieved Party may seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, threatened breach or allegation of breach, as applicable, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Each aggrieved Party hereby waives any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 13.11 (Equitable Relief) is intended, or should be construed, to limit either Party's right to equitable relief for a breach or the threatened of any other provision of this Agreement.

13.12. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by the other Party whether of a similar nature or otherwise.

13.13. No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties, their respective Affiliates and its and their successors and permitted assigns, and they shall not be construed as conferring any rights on any Third Parties.

13.14. Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.15. Relationship of the Parties. It is expressly agreed that Sanofi Kymab, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Sanofi Kymab, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

13.16. References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule means references to such Article, Section or Schedule of this Agreement, (b) references in any section to any clause are references to such clause of such section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

13.17. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. The word "will" shall be construed to have the same meaning and effect as the word "shall". References to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof. Any reference herein to any person or entity shall be construed to include the person's or entity's successors and assigns. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall apply against the Party which drafted such terms and provisions.

13.18. Performance through Affiliates. Sanofi Kymab shall have the right to exercise its rights and perform its obligations hereunder, in whole or in part, through any of its Affiliates (as long as such entity remains an Affiliate of Sanofi Kymab).

13.19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute

one and the same instrument. This Agreement may be executed and delivered in portable document format (PDF) using electronic signatures and such signatures shall be deemed to bind each Party as if they were ink signatures.

[*SIGNATURE PAGE FOLLOWS****]***

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

KYMAB LIMITED	**Rallybio IPE, LLC**
By: /s/ Gordon Tillet Name: Gordon Tillet Title: Director	By: /s/ Stephen Uden Name: Stephen Uden Title: President & COO

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, Martin W. Mackay, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 8, 2022

By: /s/ Martin W. Mackay

Martin W. Mackay, Ph.D.
Chief Executive Officer
(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, Jeffrey M. Fryer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 8, 2022

By: /s/ Jeffrey M. Fryer

Jeffrey M. Fryer, CPA
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 Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending June 30, 2022 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: August 8, 2022

By: /s/ Martin W. Mackay

Martin W. Mackay, Ph.D.
Chief Executive Officer
(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 Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending June 30, 2022 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: August 8, 2022

By: /s/ Jeffrey M. Fryer

Jeffrey M. Fryer, CPA
Chief Financial Officer
(Principal Financial Officer)