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 September 30, 2024
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 November 4, 2024, the registrant had 41,487,586 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

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 RLYB212, RLYB116, and the natural history study for our fetal and neonatal alloimmune thrombocytopenia 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 the clinical development of our product candidates, including RLYB212 and RLYB116;
- the potential of our product candidates to treat certain target diseases;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory designations allowing for priority review of our product candidates, and our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- 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 paroxysmal nocturnal hemoglobinuria and generalized myasthenia gravis;
- our reliance on third parties to conduct our clinical trials;
- enhancements to the manufacturing process for RLYB116;
- our reliance on third parties to manufacture drug substance and drug product for use in our clinical trials;
- the size and growth potential of the markets for RLYB212, RLYB116, RLYB114, RLYB332 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 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 and any subsequent offerings;
- the potential benefits of strategic collaboration agreements and arrangements, including our agreements with Johnson & Johnson, Exscientia Limited and AbCellera Biologics Inc. and our research collaboration with EyePoint Pharmaceuticals, Inc., and the expected timing of updates related thereto, including timing to achieve development candidate nominations, 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 ("U.S.") 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;

- 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, including the Medicines and Healthcare products Regulatory Agency in the United Kingdom (the “MHRA”), 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 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;

- The FDA, EMA or other comparable foreign regulatory authorities, including the MHRA, 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, including RLYB212. 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 pursue business development transactions focused on the in-license of additional product candidates or the out-license of rights to product candidates in our pipeline and collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources; and

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

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)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,320	$ 24,494
Marketable securities	49,819	85,435
Prepaid expenses and other current assets	3,091	4,860
Total current assets	78,230	114,789
Property and equipment, net	145	246
Operating lease right-of-use assets	201	346
Investment in joint venture	431	239
Total assets	$ 79,007	$ 115,620
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 583	$ 976
Accrued expenses	6,279	8,068
Operating lease liabilities	230	219
Deferred revenue	1,097	—
Total current liabilities	8,189	9,263
Operating lease liabilities, noncurrent	—	173
Total liabilities	8,189	9,436
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively; and 41,487,586 and 37,829,565 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	4	4
Preferred stock, $0.0001 par value per share; 50,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively; no shares issued or outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	352,621	341,410
Accumulated other comprehensive loss	169	15
Accumulated deficit	(281,976)	(235,245)
Total stockholders' equity	70,818	106,184
Total liabilities and stockholders' equity	$ 79,007	$ 115,620

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 SEPTEMBER 30, 2024	FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2023	FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024	FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023
Revenue:				
Collaboration and license revenue	$ 299	$ —	$ 598	$ —
Total revenue	299	—	598	—
Operating expenses:				
Research and development	8,240	13,288	34,122	37,620
General and administrative	4,125	6,075	15,364	20,200
Total operating expenses	12,365	19,363	49,486	57,820
Loss from operations	(12,066)	(19,363)	(48,888)	(57,820)
Other income:				
Interest income	986	1,545	3,405	4,699
Other income	251	92	561	227
Total other income, net	1,237	1,637	3,966	4,926
Loss before equity in losses of joint venture	(10,829)	(17,726)	(44,922)	(52,894)
Loss on investment in joint venture	637	648	1,809	1,428
Net loss	$ (11,466)	$ (18,374)	$ (46,731)	$ (54,322)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.45)	$ (1.08)	$ (1.35)
Weighted-average common shares outstanding, basic and diluted	44,593,221	40,531,497	43,170,177	40,382,625
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities	240	64	154	6
Other comprehensive gain (loss)	240	64	154	6
Comprehensive loss	$ (11,226)	$ (18,310)	$ (46,577)	$ (54,316)

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 SEPTEMBER 30, 2024 AND 2023	COMMON		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	STOCKHOLDERS' EQUITY
(in thousands, except share amounts)	**SHARES**	**AMOUNT**				
June 30, 2023	37,790,856	$ 4	$ 336,154	$ (196,629)	$ (272)	$ 139,257
Share-based compensation expense	—	—	2,634	—	—	2,634
Issuance of common stock under the stock award plan	10,000	—	—	—	—	—
Net loss	—	—	—	(18,374)	—	(18,374)
Other comprehensive gain	—	—	—	—	64	64
Balance, September 30, 2023	37,800,856	$ 4	$ 338,788	$ (215,003)	$ (208)	$ 123,581
June 30, 2024	41,487,586	$ 4	$ 350,594	$ (270,510)	$ (71)	$ 80,017
Share-based compensation expense	—	—	2,027	—	—	2,027
Net loss	—	—	—	(11,466)	—	(11,466)
Other comprehensive gain	—	—	—	—	240	240
Balance, September 30, 2024	41,487,586	$ 4	$ 352,621	$ (281,976)	$ 169	$ 70,818

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023	COMMON		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	STOCKHOLDERS' EQUITY
(in thousands, except share amounts)	**SHARES**	**AMOUNT**				
December 31, 2022	37,837,369	$ 4	$ 330,208	$ (160,681)	$ (214)	$ 169,317
Share-based compensation expense	—	—	8,371	—	—	8,371
Issuance of common stock under the stock award plan	11,219	—	—	—	—	—
Issuance of common stock under the stock purchase plan	43,423	—	209	—	—	209
Forfeiture of restricted common stock	(91,155)	—	—	—	—	—
Net loss	—	—	—	(54,322)	—	(54,322)
Other comprehensive gain	—	—	—	—	6	6
Balance, September 30, 2023	37,800,856	$ 4	$ 338,788	$ (215,003)	$ (208)	$ 123,581
December 31, 2023	37,829,565	$ 4	$ 341,410	$ (235,245)	$ 15	$ 106,184
Share-based compensation expense	—	—	6,030	—	—	6,030
Issuance of common stock upon completion of a securities purchase agreement, net of offering costs of $268	3,636,363	—	5,137	—	—	5,137
Issuance of common stock under the stock award plan	1,925	—	—	—	—	—
Issuance of common stock under the stock purchase plan	38,289	—	44	—	—	44
Forfeiture of restricted common stock	(18,556)	—	—	—	—	—
Net loss	—	—	—	(46,731)	—	(46,731)
Other comprehensive gain	—	—	—	—	154	154
Balance, September 30, 2024	41,487,586	$ 4	$ 352,621	$ (281,976)	$ 169	$ 70,818

See accompanying notes of the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)	FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024	2023
Cash Flows Used in Operating Activities:		
Net loss	$ (46,731)	$ (54,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	101	114
Net accretion of discounts/premiums on debt securities	(1,296)	(2,432)
Stock-based compensation	6,030	8,371
Loss on investment in joint venture	1,809	1,428
Changes in operating assets and liabilities:		
Prepaid expenses, right-of-use assets and other assets	1,914	(400)
Accounts payable	(393)	(623)
Accrued expenses and operating lease liabilities	(1,951)	(756)
Deferred revenue	1,097	—
Net cash used in operating activities	(39,420)	(48,620)
Cash Flows Provided By (Used In) Investing Activities:		
Purchases of marketable securities	(31,609)	(95,675)
Proceeds from maturities of marketable securities	68,674	107,924
Investment in joint venture	(2,000)	(1,500)
Net cash provided by investing activities	35,065	10,749
Cash Flows Provided By (Used In) Financing Activities:		
Proceeds from the issuance of common stock from a securities purchase agreement	5,405	—
Proceeds from the issuance of common stock under the stock purchase plan	44	209
Payments of offering costs	(268)	(138)
Net cash provided by financing activities	5,181	71
Net increase (decrease) in cash and cash equivalents	826	(37,800)
Cash and cash equivalents — beginning of period	24,494	56,958
Cash and cash equivalents — end of period	$ 25,320	$ 19,158
Supplemental Disclosures of Noncash Investing Activities:		
Property and equipment in accounts payable and accrued expenses	$ —	$ 12

See accompanying notes of the condensed consolidated financial statements

RALLYBIO CORPORATION

Notes to Unaudited Condensed Consolidated Financial Statements

1. BUSINESS AND LIQUIDITY

Rallybio Corporation and subsidiaries ("Rallybio", the "Company", "we", "our", or "us") is a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Since our launch in January 2018, we have built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in the areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. Our two most advanced programs are in clinical development: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (“FNAIT”) and RLYB116, an inhibitor of complement component 5 (“C5”), with the potential to treat several diseases of complement dysregulation. Both programs have completed Phase 1 clinical studies, and we currently plan to initiate a Phase 2 clinical trial of RLYB212 in the fourth quarter of 2024.

The Company had cash, cash equivalents and marketable securities of $75.1 million as of September 30, 2024. The Company currently expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date these unaudited condensed consolidated financial statements are issued. However, the Company does not anticipate that its current cash, cash equivalents and marketable securities as of September 30, 2024 will be sufficient to fund any of its product candidates through regulatory approval, and it will need to raise substantial additional capital to complete the development and commercialization of its product candidates, if approved. We may satisfy our future cash needs through the sale of equity securities, debt financings, corporate collaborations or license agreements, working capital lines of credit, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

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"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) promulgated by the Financial Accounting Standards Board (“FASB”).

In the opinion of the Company, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported 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, 2023 (our "Annual Report"). Our significant accounting policies are described in Note 2 of the Notes to the consolidated financial statements included in our Annual Report. There have been no new accounting policies, including the adoption of new accounting standards during the three and nine months ended September 30, 2024, unless otherwise noted below, which could be expected to materially impact the Company's unaudited condensed consolidated financial statements.

Significant Accounting Policies —

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

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

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

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

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

Restructuring
The Company accounts for restructuring charges in accordance with ASC Subtopic 420-10, *Exit or Disposal Cost Obligations.* The charges related to the workforce reduction are cash-based expenditures related primarily to severance and benefit payments, with such amounts reflected in the Company's condensed consolidated statements of operations and other comprehensive loss. For further details on the Company’s restructuring activities, please refer to Note 9 to the Company’s unaudited condensed consolidated financial statements contained in this Quarterly Report.

Recently Issued Accounting Pronouncements—In November 2023, the FASB issued ASU 2023-07, *Segment Reporting* (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). This ASU requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The amendments in ASU 2023-07 apply to public entities, including those with a single reportable segment. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The new standard should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09") which establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. The guidance should be applied on a prospective basis. For public business entities, ASU 2023-09 is effective for fiscal years beginning after December 15, 2024,

with early adoption permitted. For all other entities, the standard is effective for annual periods beginning after December 15, 2025. The Company is currently evaluating the impact on its consolidated financial statements.

3. 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 September 30, 2024 and December 31, 2023 was as follows:

		SEPTEMBER 30, 2024			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Money market funds	Level 1	$ 18,879	$ —	$ —	$ 18,879
U.S. treasury securities	Level 1	29,696	104	—	29,800
U.S. government agency securities	Level 2	19,954	66	(1)	20,019
		$ 68,529	$ 170	$ (1)	$ 68,698

		DECEMBER 31, 2023			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Money market funds	Level 1	$ 14,538	$ —	$ —	$ 14,538
U.S. treasury securities	Level 1	35,976	48	(6)	36,018
U.S. government agency securities	Level 2	51,434	31	(58)	51,407
		$ 101,948	$ 79	$ (64)	$ 101,963

The fair values of marketable securities by classification in the condensed consolidated balance sheets was as follows as of September 30, 2024 and December 31, 2023:

(in thousands)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Cash and cash equivalents	$ 18,879	$ 16,528
Marketable securities	49,819	85,435
	$ 68,698	$ 101,963

The fair values of available-for-sale debt securities as of September 30, 2024 and December 31, 2023, by contractual maturity, are summarized as follows:

(in thousands)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Due in one year or less	$ 62,297	$ 98,110
Due after one year through two years	6,401	3,853
	$ 68,698	$ 101,963

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of September 30, 2024 and December 31, 2023 was $2.0 million and $40.0 million, respectively. As of September 30, 2024, we did not have any investments in a continuous unrealized loss position for more than twelve months. As of September 30, 2024, we believe that the cost basis of our available-for-sale debt securities is recoverable. No allowance for credit losses was recorded as of September 30, 2024 and December 31, 2023.

4. BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets —
Prepaid expenses and other current assets consisted of the following as of September 30, 2024 and December 31, 2023:

(in thousands)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Research and development	$ 446	$ 2,067
Insurance	608	446
Other prepaids	286	293
Other current assets	1,751	2,054
	$ 3,091	$ 4,860

Accrued Expenses—
Accrued expenses consisted of the following as of September 30, 2024 and December 31, 2023:

(in thousands)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Research and development	$ 3,218	$ 4,123
Compensation and related expenses	2,420	3,166
Professional fees	430	332
Other accrued expenses	211	447
	$ 6,279	$ 8,068

5. STOCKHOLDERS' EQUITY

Common Stock
In April 2024, the Company entered into a Securities Purchase Agreement with Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"), pursuant to which the Company sold to JJDC, in an unregistered offering, 3,636,363 shares of its common stock, at a price of $1.82 per share, which represents a 10% premium on the Company's closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses.

The Company had 200,000,000 shares of common stock authorized as of September 30, 2024 and December 31, 2023, of which 41,487,586 and 37,829,565 shares were issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.

Preferred Stock
The Company had 50,000,000 shares of preferred stock authorized as of September 30, 2024 and December 31, 2023, of which no shares were outstanding as of September 30, 2024 and December 31, 2023.

Pre-Funded Warrants
In connection with a follow-on offering in November 2022, the Company entered into an agreement with certain investors for pre-funded warrants in lieu of common stock to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $5.9999, which represents the per share public offering price of the November 2022 follow-on offering for common stock less a $0.0001 per share exercise price for each pre-funded warrant.

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

The Company's pre-funded warrant is a freestanding instrument that does not meet the definition of a liability pursuant to ASC 480, *Distinguishing Liabilities from Equity,* and does not meet the definition of a derivative pursuant to ASC 815, *Derivatives and Hedging*. The pre-funded warrant is indexed to the Company's common stock and meets all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the pre-funded warrant was classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. All of the pre-funded warrants related to our November 2022 follow-on offering remain outstanding and unexercised as of September 30, 2024.

Share-based Compensation

Share-based compensation expense is comprised of the Company's stock options, restricted stock awards, restricted stock units and shares issued pursuant to the employee stock purchase plan, and is classified in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023 as follows:

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands)	2024	2023	2024	2023
Research and development	$ 863	$ 1,182	$ 2,404	$ 3,425
General and administrative	1,164	1,452	3,626	4,946
	$ 2,027	$ 2,634	$ 6,030	$ 8,371

2021 Equity Incentive Plan

In 2021, the board of directors adopted the Rallybio Corporation 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan initially reserved 5,440,344 shares of the Company's common stock that have been issued in respect of outstanding equity awards granted prior to the Company's initial public offering ("IPO"), and for future issuances of shares to employees, directors and consultants in the form of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on the Company's common stock. Dividend equivalents may also be provided in connection with awards under the 2021 Plan. The share pool will automatically increase on January 1st of each year until 2031, by the lesser of (i) five percent of the number of shares of the Company's common stock outstanding as of such date and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. On January 1, 2024 and January 1, 2023, the 2021 Plan share pool was automatically increased by 1,891,478 and 1,891,868 shares, respectively. As of September 30, 2024, the total number of shares of common stock that were issuable under the 2021 Plan was 8,683,135 shares, of which 2,920,490 shares remained available for future issuance.

The following table summarizes stock option activity for the nine months ended September 30, 2024:

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, 2023	4,270,544	$ 9.98	8.5	$ —
Granted	1,119,039	$ 1.89		
Forfeited	(629,829)	$ 9.19		
Expired	(25,950)	$ 12.32		
Exercised	—	$ —		
Outstanding at September 30, 2024	4,733,804	$ 8.16	7.4	$ —
Options exercisable at September 30, 2024	2,551,303	$ 10.10	6.4	$ —

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 September 30, 2024 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 nine months ended September 30, 2024 and 2023 was $1.47 per share and $4.93 per share, respectively. As of September 30, 2024, there was unrecognized share-based compensation expense related to unvested stock options of $9.3 million which the Company expects to recognize over a weighted-average period of approximately 2.1 years.

The fair value of the stock options granted during the nine months ended September 30, 2024 and 2023 was determined using the Black-Scholes option pricing model with the following assumptions:

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
Expected volatility	89.41% - 94.48%	88.38% - 92.27%
Expected term (years)	5.50 - 6.02	5.50 - 6.08
Risk free interest rate	3.93% - 4.35%	3.58% - 4.52%
Expected dividend yield	—	—
Exercise price	$1.86 - $2.40	$5.38 - $7.83

A summary of the status of the Company's unvested restricted common stock awards at September 30, 2024 and changes during the nine months ended September 30, 2024 was as follows:

Restricted Stock Awards	Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested restricted stock awards at December 31, 2023	354,394	$ 4.10
Granted	—	$ —
Vested	(248,497)	$ 3.36
Forfeited	(18,556)	$ 16.03
Outstanding unvested restricted stock awards at September 30, 2024	87,341	$ 3.66

As of September 30, 2024, there was unrecognized share-based compensation expense related to unvested restricted stock awards of $0.3 million, which the Company expects to recognize over a weighted-average period of approximately 0.5 years.

A summary of the status of the Company's unvested restricted common stock units at September 30, 2024 and changes during the nine months ended September 30, 2024 was as follows:

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2023	220,250	$ 8.55
Granted	911,856	$ 1.51
Forfeited	(101,340)	$ 7.60
Vested	(1,925)	$ 7.68
Outstanding unvested restricted stock units at September 30, 2024	1,028,841	$ 2.41

As of September 30, 2024, there was unrecognized share-based compensation expense related to unvested restricted stock units of $1.4 million, which the Company expects to recognize over a weighted-average period of approximately 1.7 years.

2021 Employee Stock Purchase Plan

In connection with the Company's IPO, the board of directors adopted the Rallybio Corporation 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which initially reserved 291,324 shares of the Company's common

stock for future issuances. The share pool will automatically increase on January 1st of each year until 2031, by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date, (ii) 582,648 shares of the Company's common stock and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. The 2021 ESPP share pool did not increase on January 1, 2024. On January 1, 2023, the 2021 ESPP share pool was automatically increased by 378,373 shares. As of September 30, 2024, the total number of shares of the Company's common stock available for future issuance under the 2021 ESPP was 834,589 shares. During the nine months ended September 30, 2024 and 2023, the Company issued 38,289 shares and 43,423 shares, respectively, under the 2021 ESPP.

The 2021 ESPP allows eligible participants to purchase shares of our common stock through authorized payroll deductions. Pursuant to the 2021 ESPP, the purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the date on which the relevant option was (i) granted and (ii) deemed exercised.

For the three and nine months ended September 30, 2024, the total share-based compensation for the 2021 ESPP was $10 thousand and $64 thousand, respectively. For the three and nine months ended September 30, 2023 the total share-based compensation for the 2021 ESPP was $33 thousand and $155 thousand, respectively.

6. 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 September 30, 2024 and 2023, the Company funded $0.5 million and $0.8 million, respectively, associated with the Company's commitment and its share of REV-I development. For the nine months ended September 30, 2024 and 2023, the Company funded $2.0 million and $1.5 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 nine months ended September 30, 2024 and 2023. While the Company held a 50% interest in the joint venture as of September 30, 2024, based on management's analysis, the Company is not the primary beneficiary of REV-I and accordingly, the entity is not consolidated in the Company's condensed consolidated financial statements.

For the three and nine months ended September 30, 2024, the Company recorded its allocable share of REV-I's losses, which totaled $0.6 million and $1.8 million, respectively. For the three and nine months ended September 30, 2023, the Company recorded its allocable share of REV-I's losses which totaled $0.6 million and $1.4 million, respectively. These losses were recorded 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 September 30, 2024 and December 31, 2023 was $0.4 million and $0.2 million, respectively, which was recorded in investment in joint venture in the accompanying condensed consolidated balance sheets.

7. 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 September 30, 2024 and December 31, 2023 there were no amounts accrued related to termination charges.

8. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share for the three and nine months ended September 30, 2024 and 2023 was calculated as follows:

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands except share and per share amounts)	2024	2023	2024	2023
Net loss	$ (11,466)	$ (18,374)	$ (46,731)	$ (54,322)
Weighted-average number of common shares outstanding, basic and diluted	44,593,221	40,531,497	43,170,177	40,382,625
Net loss per common share, basic and diluted	$ (0.26)	$ (0.45)	$ (1.08)	$ (1.35)

Basic net loss per share of common stock is based on the weighted-average number of shares of common stock outstanding during the period. Pre-funded warrants to purchase 3,333,388 shares of common stock that were issued in connection with the November 2022 follow-on offering were included in the weighted-average number of common shares outstanding for the three and nine months ended September 30, 2024 and 2023. The weighted average number of common shares outstanding diluted for the three and nine months ended September 30, 2024 and 2023 excludes approximately 5.8 million and 5.0 million stock options and unvested restricted stock awards and units, respectively, which were not dilutive.

9. RESTRUCTURING

On February 6, 2024, the Company announced a prioritization of its portfolio and a workforce reduction to focus resources primarily on the continued development of RLYB212.

As part of this effort, the Company eliminated approximately 45% of its positions. As a result of these actions, the Company incurred charges of approximately $3.3 million of which $2.0 million was included in research and development expenses and $1.3 million was included in general and administrative expenses, with such amounts reflected in the condensed consolidated statements of operations and comprehensive loss. The charges related to the workforce reduction are cash-based expenditures related primarily to severance and benefit payments. The Company recognized all such charges during the three months ended March 31, 2024, with such amounts reflected in the condensed consolidated statements of operations and comprehensive loss. The accrued restructuring liability is included in accrued expenses on the condensed consolidated balance sheets as of September 30, 2024. Substantially all restructuring payments are expected to be completed by December 31, 2024.

The following table summarizes the restructuring accrual activity as of September 30, 2024:

(in thousands)	SEPTEMBER 30, 2024
Beginning accrued severance	$ —
Severance incurred during the period	3,279
Severance paid and adjustments made during the period	2,906
	$ 373

10. COLLABORATION AND LICENSE AGREEMENTS

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

The Company has an ongoing multinational FNAIT natural history study to determine the frequency of women at higher FNAIT risk among pregnant women of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. In this study, participants

are screened to determine whether they are HPA-1a negative, positive for HLA-DRB3*01:01 and for the absence of HPA-1a alloantibodies. Subject to the results of the initial screenings, a final screening may be conducted to detect whether the fetus is HPA-1a positive. The FNAIT natural history study is expected to screen up to 30,000 pregnant women of different racial and ethnic characteristics in North America and Europe. In addition, the Company is a sponsor of a planned Phase 2 FNAIT clinical trial that will include collection of certain natural history data.

Pursuant to the Collaboration Agreement, the Company received an upfront payment of $0.5 million from J&J for the information dissemination and data provision services under the agreement. In addition, the Company is eligible for payments upon the achievement of certain enrollment-related events, totaling up to $0.7 million. The Company is also eligible to receive additional payments upon certain triggers related to the companies' FNAIT studies.

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

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

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

In April 2024, the Company also entered into a Securities Purchase Agreement with JJDC. Under the terms of the Securities Purchase Agreement, JJDC made an equity investment purchasing 3,636,363 shares of common stock with a par value of $0.0001 per share for a share purchase price of $1.82 per share which includes a 10% premium for an aggregate purchase price of $6.6 million. The Securities Purchase Agreement contains provisions related to the registration of the shares and the restriction on the sale or transfer of the shares for a period of time. The Company determined the Collaboration Agreement and Securities Purchase Agreement represented combined agreements. In accordance with ASC 606 and ASC Topic 820, *Fair Value Measurement* ("ASC 820"), total consideration of $1.2 million for the shares of common stock from the Securities Purchase Agreement, which represents the premium of $0.7 million and discount for lack of marketability of $0.5 million, has been allocated to revenue and will be recognized over the two year expected performance period.

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

The Company recognized $0.3 million and $0.6 million, respectively, in revenue during the three and nine months ended September 30, 2024, related to data collection and data submission with the identified performance obligations, and the premium and discount allocated to revenue from the sale of the common stock to JJDC. The remaining revenue is included in deferred revenue as of September 30, 2024, and will be recognized as the performance obligations are satisfied.

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

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 on Form 10-K for the year ended December 31, 2023 (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 comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Since our launch in January 2018, we have built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in the areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. Our two most advanced programs are in clinical development: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia ("FNAIT") and RLYB116, an inhibitor of complement component 5 ("C5"), with the potential to treat several diseases of complement dysregulation. Both programs have completed Phase 1 clinical studies, and we currently plan to initiate a Phase 2 clinical trial of RLYB212 in the fourth quarter of 2024.

Maternal Fetal Blood Disorders

RLYB212 is a monoclonal anti-HPA-1a antibody for the prevention of FNAIT, a potentially life-threatening rare hematological disease that impacts fetuses and newborns. In the fourth quarter of 2024, the European Medicines Agency (the "EMA") and the United Kingdom's Medicines and Healthcare products Regulatory Agency (the "MHRA") approved our clinical trial applications ("CTAs") for the Phase 2 clinical trial of RLYB212 and we are planning to initiate the trial in the fourth quarter of 2024.The Phase 2 trial, which will be conducted in Belgium, the Netherlands, Norway, Sweden, and the UK, is designed to assess the pharmacokinetic ("PK") and safety of RLYB212, a monoclonal anti-HPA-1a antibody, in a total of eight pregnant women at higher risk for HPA-1a alloimmunization and FNAIT. Secondary objectives include assessments of pregnancy and neonatal/infant outcomes, and the occurrence of emergent HPA-1a alloimmunization. Subcutaneous administration of RLYB212 will be initiated by Gestational Week 16 and continue every 4 weeks through parturition. Following completion of the Phase 2 dose confirmation trial and consultation with regulatory authorities, we expect to initiate a Phase 3 registrational trial. Both the U.S. Food and Drug Administration (the "FDA") and EMA have designated RLYB212 as an orphan drug. Orphan drug designation offers certain incentives including tax credits, marketing exclusivity upon any approval, fee waivers, and the ability to interact with both agencies to receive specialized regulatory advice and assistance.

We have completed two RLYB212 clinical studies: a Phase 1 first-in-human clinical study and a Phase 1b proof of concept clinical study. The Phase 1 first-in-human clinical study was a single-blind, placebo-controlled study that investigated the safety and PK of subcutaneous ("SC") administration of RLYB212 in HPA-1a negative healthy participants. The clinical study included a single dose cohort and a multiple dose cohort. In the multiple dose cohort, subjects received SC RLYB212 or placebo every 2 weeks for 12 weeks. We reported results from the multi-dose cohort in the fourth quarter of 2023. The data and our clinical pharmacology modeling predictions support a once monthly dosing regimen for the Phase 2 clinical trial.

In the first quarter of 2023, we announced RLYB212 achieved proof-of-concept in the Phase 1b study. In this study, SC RLYB212 administration produced a dose-dependent, rapid and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both dose groups meeting the pre-specified proof-of-concept criteria of ≥ 90% reduction in mean platelet elimination half-life. Mean platelet elimination half-life was 5.8 hours (0.09mg dose) and 1.5 hours (0.29mg dose) for RLYB212 compared to 71.7 hours for placebo. In both Phase 1 studies, RLYB212 was observed to be generally well-tolerated with no reports of serious or severe adverse events.

We are also conducting a prospective, non-interventional, multinational FNAIT natural history study. This study is designed to screen up to 30,000 pregnant women presenting at the Gestational Week 10 to 14 prenatal visit to determine the frequency of women at higher FNAIT risk among pregnant women of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. Subject to discussion with regulatory authorities, we expect that data from this study will contribute to a control dataset for a future single-arm Phase 3 registrational trial for RLYB212. The FNAIT natural history study will also operationalize *de novo* the laboratory test paradigm for FNAIT risk and generate FNAIT laboratory test performance data that we plan to use for future regulatory discussions.

Screening in the natural history study is ongoing, with more than 13,000 pregnant women screened as of November 1, 2024. In connection with the initiation of the Phase 2 trial, we have transitioned European sites from the natural history study to the Phase 2 clinical trial, where sites will continue to collect natural history data in women who do not receive RLYB212. While the North American natural history study sites have continued screening activities as planned, we have seen an anticipated reduction in screening rates at the European sites during their transition into the Phase 2 clinical trial. The totality of natural history data from both studies is designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population that can serve as a control arm for the planned Phase 3 trial.

In April 2024, we entered into a collaboration agreement (the “Collaboration Agreement”) with Johnson & Johnson, through its wholly-owned subsidiary, Momenta Pharmaceuticals, Inc. (“J&J”), pursuant to which we and J&J will support the development of complementary therapeutic approaches aimed at reducing the risk of FNAIT. Under the Collaboration Agreement, we will share certain aggregated, anonymized data with J&J, collected from the FNAIT natural history study and our planned RLYB212 Phase 2 clinical trial that will be restricted to collection of certain natural history data in support of the natural history study. We also agreed to disseminate information to our FNAIT study sites related to J&J’s and its affiliates’ research and development of complementary therapeutic approaches aimed at reducing the risk of FNAIT. Pursuant to the agreement, we received an upfront payment of $0.5 million from J&J. In addition, we are eligible for payments upon the achievement of certain enrollment-related events, totaling up to $0.7 million. We are also eligible to receive additional payments upon certain triggers related to the companies' FNAIT studies. In addition, we received an equity investment of $6.6 million from Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"). See "Liquidity and Capital Resources - Sources of Liquidity" below. In connection with the registration requirements and the restrictions on the sale or transfer of the common stock sold, we expect to recognize up to an additional $1.2 million of revenue.

Complement Dysregulation

We are also developing therapies that address diseases of complement dysregulation, including paroxysmal nocturnal hemoglobinuria ("PNH"), antiphospholipid syndrome ("APS") and generalized myasthenia gravis ("gMG"). RLYB116 is a novel, potentially long-acting, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-related diseases. RLYB114 is a pegylated C5 inhibitor in development for complement-mediated ophthalmic disorders.

We have completed a Phase 1 clinical study in healthy participants that included the study of RLYB116 as a single ascending dose ("SAD") and a multiple ascending dose ("MAD"). The SAD portion of the RLYB116 clinical study included five cohorts with a dose ranging from 2mg up to 300mg. Data from the SAD portion of the study showed that all study participants that were administered a single 1 mL SC injection of 100 mg of RLYB116 (n=6) demonstrated a reduction in free C5 greater than 99% within 24 hours of dosing. Subcutaneously administered RLYB116 in the SAD portion of the study was observed to be generally well-tolerated at the 100 mg dose, with mild adverse events and no drug-related serious adverse events reported.

The MAD portion of the RLYB116 Phase 1 study included an adaptive single-blind design with a 4-week treatment duration to evaluate the safety, tolerability, PK, and pharmacodynamics ("PD") of RLYB116 with multiple dose SC administration. The MAD portion of the study included 4 cohorts: Cohort 1 (weekly dosing of 100 mg), Cohort 2 (3 doses of 100 mg the first week followed by weekly dosing), Cohort 3 (150 mg weekly dosing reduced to 125 mg weekly dosing) and Cohort 4 (75 mg twice the first week followed by 100 mg twice per week) with post-treatment / study follow-up for 10 weeks. In December 2023, we reported data from the MAD portion of the study that demonstrated a 100 mg low volume (1 mL) once-a-week dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at Day 29 with measurement prior to the last dose. The reduction from pre-treatment free C5 at 24 hours after the first

dose of 100 mg was greater than 99%. RLYB116 administered in the MAD portion of the study as a 100 mg once-a-week dose was also observed to be generally well tolerated.

Based on the data generated in the MAD portion of the study, we initiated additional manufacturing activities and biomarker analyses. The manufacturing work on RLYB116 was completed in the third quarter of 2024 and drug substance characterization data indicates that Rallybio's efforts to enhance the manufacturing process have been successful. In addition, we have conducted additional complement biomarker analyses that when taken together with the MAD data indicate that RLYB116 led to greater sustained reductions in free C5 than initially indicated and lead us to believe that there is an opportunity to pursue indications beyond gMG such as PNH and APS at doses tested in the Phase 1 MAD study. In December 2024, we expect to provide updates on the manufacturing process enhancements and biomarker characterization, as well as future plans for RLYB116.

In February 2023, we entered into a collaboration with EyePoint Pharmaceuticals, Inc. ("EyePoint") and are using EyePoint's proprietary technology for sustained intraocular drug delivery, with the initial focus on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss. EyePoint has demonstrated feasibility for sustained delivery of Rallybio's inhibitor of C5 using EyePoint's proprietary intraocular drug delivery technology and is working on optimization.

Hematological Disorders
In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit Matriptase-2 ("MTP-2"). The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. In the first quarter of 2024, we completed nonclinical studies that demonstrated favorable tolerability, dose-dependent PK and sustained PD effects with RLYB332, a long-acting version of the RLYB331 anti-Matriptase-2 antibody. These data will be presented at the American Society of Hematology ("ASH") Annual Meeting which will be held December 7 – 10 in San Diego, CA. These findings support the continued development of RLYB332 as a potentially best-in-class therapeutic for treating diseases of iron overload. We continue to evaluate non-dilutive options to further advance this program, including potential partnerships.

Metabolic Disorders
In collaboration with Exscientia Limited ("Exscientia"), we continue to work toward the selection of a small molecule development candidate to advance into the clinic targeting Ectonucleotide Pyrophosphatase/ Phosphodiesterase 1 ("ENPP1") for the treatment of patients with hypophosphatasia ("HPP"). Proof of mechanism studies are in progress with a leading global HPP expert. We expect to achieve development candidate nomination of a small molecule inhibitor of ENPP1 for the treatment of patients with HPP in the fourth quarter of 2024. In addition, data from an early lead compound in a nonclinical model of HPP was presented at the American Society for Bone and Mineral Research meeting in September 2024. The data demonstrated that oral dosing of REV101 to adult HPP mice lowered inorganic pyrophosphate (PPi) by 30%, leading to improvements in mineralization of long and vertebrate bones. Furthermore, data showed that ENPP1 inhibition was safe and generally well-tolerated. Data also showed, for the first time, that ENPP1 is a druggable target for later-onset HPP.

In December 2022, we entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration will combine AbCellera Biologics Inc.'s ("AbCellera's") antibody discovery engine with our clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients. The first program is focused on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Our Operations
Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the Company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates, preparing for and conducting clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our programs. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

Since our inception, we have funded our operations primarily through equity financings. From our inception and prior to our initial public offering ("IPO"), we received proceeds of approximately $182.5 million from equity financings. In August 2021, we closed our IPO and issued and sold 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.

In November 2022, we completed a follow-on offering of approximately $54.8 million pursuant to which we issued 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at a price of $6.00 per share and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $5.9999, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

In April 2024, we entered into a Securities Purchase Agreement with JJDC pursuant to which we sold to JJDC, in an unregistered offering, 3,636,363 shares of our common stock at a price of $1.82 per share, which represents a 10% premium on the Company's closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses. We agreed, among other things, to file with the Securities and Exchange Commission (the "SEC") a registration statement covering the resale of the shares, which we filed on May 10, 2024.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of $75.1 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 middle of 2026. 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 $11.5 million and $46.7 million for the three and nine months ended September 30, 2024, respectively, and $18.4 million and $54.3 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $282.0 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We have not commercialized any products and have never generated revenue from the commercialization of any product. 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 over time if and as we:

- advance our planned Phase 2 clinical trial for RLYB212;
- advance our FNAIT natural history study and any other studies to support our development program and related regulatory submissions for RLYB212;
- plan for and conduct any future clinical trials for RLYB116 and any of our other product candidates;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- advance our discovery and preclinical development activities for our product candidates;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate quantities of our product candidates, including 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.

Components of Results of Operations

Revenue

We do not have any product candidates approved for sale and have not generated any revenue from product sales. Our collaboration and license revenue to date is related to data collection and data submission performance obligations pursuant to the two-year Collaboration Agreement with J&J to facilitate the advancement of research into products to address unmet needs relating to FNAIT. Pursuant to the Collaboration Agreement, we received an upfront payment of $0.5 million from J&J for the information dissemination and data provision services under the agreement. In addition, we are eligible for payments upon the achievement of certain enrollment-related events, totaling up to $0.7 million. We are also eligible to receive additional payments upon certain triggers related to the companies' FNAIT studies.

We evaluated the agreement and determined it was within the scope of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). We determined there were performance obligations as follows:

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

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

In April 2024, we also entered into a Securities Purchase Agreement with JJDC. Under the terms of the Securities Purchase Agreement, JJDC made an equity investment purchasing 3,636,363 shares of common stock with a par value of $0.0001 per share for a share purchase price of $1.82 per share which includes a 10% premium for an aggregate purchase price of $6.6 million. The Securities Purchase Agreement contains provisions related to the registration of the shares and the restriction on the sale or transfer of the shares for a period of time. We determined the Collaboration Agreement and Securities Purchase Agreement represented combined agreements. In accordance with ASC 606 and ASC Topic 820, total consideration of $1.2 million for the shares of common stock from the Securities Purchase Agreement, which represents the premium of $0.7 million and discount for lack of marketability of $0.5 million, has been allocated to revenue and will be recognized over the two year expected performance period.

Operating Expenses

Research and Development Expenses

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

- external research and development expenses incurred under agreements with third parties, such as contract research organizations ("CROs") as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including expenses related to the manufacturing scale-up and fees paid to contract manufacturing organizations ("CMOs");

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

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

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

We do not allocate employee costs, 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 continue investing in our research and development activities for the foreseeable future as we continue the development of our product candidates and the related 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, our ongoing assessments as to each product candidate’s commercial potential and the availability of capital. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly as our programs advance to later stages of development. We anticipate that our expenses may fluctuate from quarter to quarter, 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;
- 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;
- receipt of marketing approvals from applicable regulatory authorities;
- 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, 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, Net
Total other income, net, includes interest income earned on cash, cash equivalents and marketable securities, and 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 consolidated balance sheets for equity method investments for which it does not have a controlling interest in.

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations:

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		
(in thousands)	**2024**	**2023**	**CHANGE**
Revenue:			
Collaboration and license revenue	$ 299	$ —	$ 299
Total revenue	299	—	299
Operating expenses:			
Research and development	8,240	13,288	(5,048)
General and administrative	4,125	6,075	(1,950)
Total operating expenses	12,365	19,363	(6,998)
Loss from operations	(12,066)	(19,363)	7,297
Total other income, net	1,237	1,637	(400)
Loss before equity in losses of joint venture	(10,829)	(17,726)	6,897
Loss on investment in joint venture	637	648	(11)
Net loss	$ (11,466)	$ (18,374)	$ 6,908

Revenue

Collaboration and license revenue was $0.3 million during the three months ended September 30, 2024. There was no collaboration and license revenue during the three months ended September 30, 2023. The increase of $0.3 million in 2024 as compared to 2023 was related to our entrance into the Collaboration Agreement with J&J

in the second quarter of 2024 and the recognition of revenue related to the collaboration performance obligations.

Operating Expenses

Research and Development Expenses

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

(in thousands)	FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2024	2023	CHANGE
Direct research and development by program			
RLYB212	$ 5,189	$ 5,666	$ (477)
RLYB116	(147)	2,654	(2,801)
Other program candidates	429	895	(466)
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	2,572	3,786	(1,214)
Other expenses	197	287	(90)
Total research and development expenses	$ 8,240	$ 13,288	$ (5,048)

Research and development expenses were $8.2 million for the three months ended September 30, 2024, compared to $13.3 million for the three months ended September 30, 2023. The decrease of $5.0 million in 2024 as compared to 2023 was primarily due to:

- a $2.8 million decrease in RLYB116 development costs, primarily related to a decrease in clinical and other research and development costs.
- a $1.2 million decrease in payroll and personnel-related costs, primarily due to the workforce reduction, effective March 6, 2024; and
- a $0.5 million decrease in RLYB212 development costs, primarily related to a decrease in manufacturing costs, which was largely offset by an increase in clinical and other research and development costs.

General and administrative expenses were $4.1 million and $6.1 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of $2.0 million in 2024 as compared to 2023 was primarily due to:

- a $1.1 million decrease in other related general and administrative expenses, including a reduction in consulting fees; and
- a $0.9 million decrease in payroll and personnel-related costs, primarily related to the workforce reduction, effective March 6, 2024, in addition to lower ongoing headcount in 2024 as compared to 2023.

Total Other Income, Net

Total other income, net, for the three months ended September 30, 2024 was $1.2 million compared to $1.6 million for the three months ended September 30, 2023. The change was primarily related to a decrease in interest income from marketable securities due to a lower cash balance.

Loss On Investment In Joint Venture

Loss on investment in joint venture for both the three months ended September 30, 2024 and 2023 was $0.6 million, respectively.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations:

(in thousands)	FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024	2023	CHANGE
Revenue:			
Collaboration and license revenue	$ 598	$ —	$ 598
Total revenue	598	—	598
Operating expenses:			
Research and development	34,122	37,620	(3,498)
General and administrative	15,364	20,200	(4,836)
Total operating expenses	49,486	57,820	(8,334)
Loss from operations	(48,888)	(57,820)	8,932
Total other income, net	3,966	4,926	(960)
Loss before equity in losses of joint venture	(44,922)	(52,894)	7,972
Loss on investment in joint venture	1,809	1,428	381
Net loss	$ (46,731)	$ (54,322)	$ 7,591

Revenue

Collaboration and license revenue was $0.6 million during the nine months ended September 30, 2024. There was no collaboration and license revenue during the nine months ended September 30, 2023. The increase of $0.6 million in 2024 as compared to 2023 was related to our entrance into the Collaboration Agreement with J&J in the second quarter of 2024 and the recognition of revenue related to the collaboration performance obligations.

Operating Expenses

Research and Development Expenses

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

(in thousands)	FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024	2023	CHANGE
Direct research and development by program			
RLYB212	$ 17,668	$ 17,487	$ 181
RLYB116	4,290	6,396	(2,106)
Other program candidates	1,611	1,940	(329)
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	9,897	11,131	(1,234)
Other expenses	656	666	(10)
Total research and development expenses	$ 34,122	$ 37,620	$ (3,498)

Research and development expenses were $34.1 million for the nine months ended September 30, 2024, compared to $37.6 million for the nine months ended September 30, 2023. The decrease of $3.5 million in 2024 as compared to 2023 was primarily due to:

- a $2.1 million decrease in RLYB116 development costs, primarily related to a decrease in clinical and other research and development costs, which was partially offset by an increase in manufacturing costs; and

- a $1.2 million decrease in payroll and personnel-related costs, primarily due to the workforce reduction, effective March 6, 2024.

General and Administrative Expenses
General and administrative expenses were $15.4 million and $20.2 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $4.8 million in 2024 as compared to 2023 was primarily due to:

- a $3.1 million decrease in consulting fees, director and officer insurance premiums, professional fees and other related general and administrative expenses; and
- a $1.7 million decrease in payroll and personnel-related costs, primarily related to the workforce reduction, effective March 6, 2024, in addition to lower ongoing headcount in 2024 as compared to 2023.

Total Other Income, Net
Total other income, net, for the nine months ended September 30, 2024 was $4.0 million compared to $4.9 million for the nine months ended September 30, 2023. The change was primarily related to a decrease in interest income from marketable securities due to a lower excess cash balance.

Loss On Investment In Joint Venture
Loss on investment in joint venture for the nine months ended September 30, 2024 was $1.8 million compared to $1.4 million for the nine months ended September 30, 2023.

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.

In August 2022, we filed a Registration Statement on Form S-3 (the "Shelf") with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $300.0 million. The Shelf was declared effective on August 15, 2022. The Company also simultaneously entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"). In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time at prices through Cowen acting as our agent. Pursuant to the Sales Agreement, sales of our common stock, if any, will be made in sales deemed to be "at the market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"). Under the Sales Agreement, Cowen will be entitled to compensation equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of September 30, 2024, we had not sold any shares of common stock pursuant to the Sales Agreement.

In November 2022, we completed a follow-on offering of approximately $54.8 million consisting of 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at the price of $6.00 per share, and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $5.9999, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

In April 2024, we entered into a Securities Purchase Agreement with JJDC, pursuant to which we sold to JJDC in an unregistered offering, 3,636,363 shares of our common stock at a price of $1.82 per share, which represents a 10% premium on the Company's closing stock price on April 9, 2024, for aggregate gross proceeds of approximately $6.6 million, before deducting offering expenses. We agreed, among other things, to

file with the SEC a registration statement covering the resale of the shares within 120 days following the closing of the offering. We filed this registration statement on May 10, 2024.

As of September 30, 2024, we had $75.1 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 middle of 2026. This estimate and our expectation to advance the 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.

Management has implemented cash preservation initiatives including conducting a prioritization of its research and development activities with a primary focus on RLYB212, reviewing certain discretionary expenses and managing the timing of other development activities. However, 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.

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;
- 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 regulatory designations allowing for priority review and any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the cost and timing of the manufacture and supply of non-clinical and clinical trial material for RLYB212, RLYB116 and our 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;
- the cost of making royalty, milestone or other payments under our current or any future in-license agreements;

- our ability to maintain our collaborations with Exscientia and AbCellera on favorable terms and establish any new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies; and
- the costs of operating as a public company.

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

Cash Flows

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

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (39,420)	$ (48,620)
Net cash provided by investing activities	35,065	10,749
Net cash provided by financing activities	5,181	71
Net increase (decrease) in cash and cash equivalents	$ 826	$ (37,800)

Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities was $39.4 million as compared to $48.6 million for the nine months ended September 30, 2023. The decrease in net cash used in operating activities for the nine months ended September 30, 2024 was primarily related to a decrease in research and development and general and administrative activities and changes in working capital.

Investing Activities

Net cash provided by investing activities was $35.1 million for the nine months ended September 30, 2024 as compared to $10.7 million of net cash provided by investing activities for the nine months ended September 30, 2023. The increase of $24.3 million in net cash provided by investing activities was primarily related to proceeds of $68.7 million from maturities of highly-rated debt securities, partially offset by purchases of highly-rated debt securities of $31.6 million during the nine months ended September 30, 2024, as compared to proceeds from maturities of highly-rated debt securities of $107.9 million, partially offset by purchases of highly-rated debt securities of $95.7 million during the nine months ended September 30, 2023.

Financing Activities
Net cash provided by financing activities during the nine months ended September 30, 2024 was $5.2 million, representing proceeds from the issuance of common stock pursuant to the Securities Purchase Agreement with JJDC, after deducting offering costs and accounting for the total consideration allocation related to the Collaboration Agreement of $1.2 million. Net cash provided by financing activities during the nine months ended September 30, 2023 was $0.1 million, representing proceeds from the issuance of common stock under the Rallybio Corporation 2021 Employee Stock Purchase Plan, partially offset by offering cost payments made related to our November 2022 follow-on offering.

Contractual Obligations
There have been no other material changes in our contractual obligations and commitments during the nine months ended September 30, 2024 from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations” in our Annual Report.

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 of America. 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 the 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 policy is the 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 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 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 September 30, 2024 and December 31, 2023, 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 September 30, 2024. 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 Securities and Exchange Commission's (the "SEC") 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 September 30, 2024, 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.

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." 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 we have incurred significant operating losses since inception, including net losses of $11.5 million and $46.7 million for the three and nine months ended September 30, 2024, respectively, and $18.4 million and $54.3 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $282.0 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the Company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for and conducting clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our programs and our Phase 1 clinical studies for RLYB212 and RLYB116, and planned Phase 2 clinical trial for RLYB212. 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 and operate our business. The costs of advancing product candidates through each clinical phase tend to increase substantially over the duration of the clinical development process. The total costs to advance 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 our planned Phase 2 clinical trial for RLYB212;
- advance our FNAIT natural history study, and any other studies to support our development program and related regulatory submissions for RLYB212;
- plan for and conduct any future clinical trials for RLYB116 and any of our other product candidates;

- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- advance our discovery and preclinical development activities for our product candidates;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate quantities of our product candidates, including 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 the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, execute our business plan or continue our operations.

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 or any of our other product candidates. In addition, we are obligated to make certain payments under our agreements with AbCellera, Affibody AB ("Affibody"), Prophylix AS ("Prophylix"), Swedish Orphan Biovitrum AB (Publ) ("Sobi"), and Kymab Limited's ("Sanofi"), including milestone and royalty payments in connection with achievement of certain development and commercial milestones as well as the sale of resulting products under such agreements. We may also spend significant capital to develop laboratory tests, 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 September 30, 2024, will be sufficient to fund our operating expenses and capital expenditure

requirements into the middle of 2026. 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;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities, including any regulatory designations allowing for priority review and any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the cost and timing of the manufacture and supply of non-clinical and clinical trial material for RLYB212, RLYB116 and our 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 identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the cost of filing, prosecuting, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- the cost of making royalty, milestone or other payments under our current or any future in-license agreements;
- our ability to maintain our collaborations with Exscientia and AbCellera on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies; and
- the costs of operating as a public company.

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, uncertain geopolitical events, such

as the war in Ukraine and conflict in Israel, have impacted the global economy, and a severe or prolonged economic downturn could result in a variety of challenges for our business, including disruptions in the financial markets, which could adversely impact our ability to raise additional capital when needed or on 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, including sales of our common stock pursuant to the Sales Agreement with Cowen and Company, LLC, each shareholder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. Any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. If we raise additional funds through collaborations, strategic alliances or 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.

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 the 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 our product candidates, 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

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 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. Any delays in the advancement of our clinical trials could impact our product development timelines, result in increased costs, affect our ability to obtain marketing approval 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 product candidates will depend on several factors, including the following:

- successful and timely initiation of preclinical studies, and successful and timely initiation of, enrollment in, and completion of our clinical trials with results that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations within the timeframes we have projected;
- regulatory grants of authorization to proceed under investigational new drug applications or CTAs such that we can commence planned or future clinical trials of our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- 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;
- 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.

We may expand 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 venture with Exscientia and our strategic alliance with AbCellera. 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 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 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;
- 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, we could encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board ("DSMB") for such trial. Such authorities may impose a suspension or termination or recommend an alteration to clinical trials due to several factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, the identification of safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions.

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

Our lead product candidates, RLYB212 and RLYB116, are still in early clinical 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, including our natural history study for our FNAIT program, 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 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 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, 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 1b clinical study for RLYB212 was 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 observed in such study will be repeated in larger and more advanced clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and post hoc analysis of results may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. We have completed Phase 1 clinical studies for RLYB212 and RLYB116, however, even if we complete later clinical trials as planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

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 trials 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, including the MHRA, 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 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 30,000 pregnancies are at high risk for FNAIT in the United States, Canada, the United Kingdom ("UK"), 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 pregnant women 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, including the MHRA, 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, including RLYB212. 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 Premarket 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, in

recent 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.

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 the FDA's 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 the Priority Medicines ("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 ("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 Committee for Medicinal Products for Human Use 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 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 a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval there can be no assurance that such submission or application will be accepted or that the FDA will determine that the product candidate is eligible for or grant accelerated approval. A failure to obtain any planned accelerated approval for our product candidates would result in a longer time period to commercialization of our product candidates, if approved, could increase the cost of development of our product candidates and could harm our competitive position in the marketplace. If we receive accelerated approval for any of our product candidates, the FDA may withdraw accelerated approval if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to

verify such benefit or if such trial is not conducted with due diligence. Withdrawal of any accelerated approval could substantially harm our business.

Although RLYB212 has received FDA designation as rare pediatric disease drug products, any marketing application we submit for RLYB212 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 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 trials 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.
If any product candidate is approved for marketing, coverage and reimbursement for any such product by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, and other third-party payors would be essential for most patients to be able to afford the prescription medication. Our ability to achieve acceptable levels of coverage and reimbursement for products or procedures using our products 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 and may be decreased or eliminated in the future.

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

reimbursement for any 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.

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

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and reimbursement will be obtained or will be consistent across payors. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. If coverage or reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

We 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 of 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, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product, sponsor's data or submit the application as a biosimilar application. 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 an abbreviated new drug application ("ANDA") 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 pursue business development transactions focused on the in-license of additional product candidates or the out-license of rights to product candidates in our pipeline and collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

We acquired all rights to 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 RLYB332, and have entered into a joint venture with Exscientia for the development of small molecule therapeutics for rare diseases, a discovery and collaboration agreement with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases, and a research collaboration with EyePoint to explore and assess the viability of utilizing our inhibitor of C5 in EyePoint's proprietary technology for sustained intraocular delivery. 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 product candidates or technologies or able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

Our reliance on a central team consisting of a limited number of employees and third parties who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.
As of September 30, 2024, we had 25 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 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 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.

Third-party manufacturers may fail to comply with cGMP regulations or similar regulatory requirements outside the United States. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our

clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Moreover, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

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

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

Any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

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

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

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 CRO terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management’s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired

clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

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.

Beyond the ACA, there have been ongoing healthcare reform efforts. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act (“IRA”) of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D, with varying implementation dates. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and Part D drugs (with the first list of drugs announced in 2023). Subsequent to the enactment of the IRA, in 2022, the Biden administration released an executive order directing the U.S. Department of Health and Human Services to report on how the Center for Medicare and Medicaid Innovation (“CMMI”) could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. The report was issued in 2023 and proposed various models that CMMI is currently developing which seek to lower the cost of drugs, promote accessibility, and improve quality of care. One model would adjust Part B payments for drugs approved by FDA under the accelerated approval pathway to encourage timely confirmatory trial completion.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to 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 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

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 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

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. 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; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- U.S. laws and regulations prohibiting bribery and corruption, such as the U.S. Foreign Corrupt Practices Act of 1977 ("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 ("GDPR") which imposes obligations and restrictions on the collection, use, and disclosure of personal data relating to individuals located in the EU and the EEA (including health data). See “—Our business operations may subject us to data protection laws, including the GDPR, the UK GDPR, the California Consumer Privacy Act (the "CCPA") and other similar laws."

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

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

Our business operations may subject us to data protection laws, including the GDPR, the UK GDPR, the CCPA and other similar laws.

The GDPR and UK GDPR apply to companies established in the EEA and UK, respectively, as well as to companies that are not established in the EEA or UK, respectively, and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA or UK, respectively. If we conduct clinical trial programs in the EEA or UK (whether the trials are conducted directly by us or through a clinical vendor or collaborator) or enter into research collaborations involving the monitoring of individuals in the EEA or UK, or market our products to individuals in the EEA or UK, we will be subject to the GDPR or UK GDPR, as applicable. The GDPR and UK GDPR put 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 and UK, respectively, short timelines for data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals) of data breaches, and limitations on retention of information. The GDPR and UK GDPR also put 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 or UK 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 in the case of GDPR or £17.5 million in the case of UK GDPR or, in each case, up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

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

These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the United States. 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. Other countries outside of the EEA and UK maintain different privacy laws that we are subject to which may further increase our costs of compliance and expose us to greater legal risk.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. While we do not believe that we are directly subject to HIPAA as either a "covered entity" or

"business associate," U.S. sites at which we conduct clinical trials are likely to be covered entities and thus must ensure that they obtain adequate patient authorization or establish another basis under HIPAA to disclose a clinical trial subject's individually identifiable health information to us and other entities participating in our clinical trials.

In the United States, the CCPA came into effect in January 2020 and was expanded by the California Privacy Rights Act, which took effect on January 1, 2023 (collectively, "CCPA"), and which, collectively, (i) requires certain disclosures to California individuals; (ii) increases the privacy and security obligations of entities handling certain personal information; and (iii) affords such individuals, in certain situations, abilities to request the erasure of personal information, opt out of certain sales of personal information, opt out of the "sharing" of personal information (*i.e.*, disclosing of personal information for cross-context behavioral advertising), and limit the use and disclosure of "sensitive personal information" for purposes other than those for which it was disclosed, among others. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Because we have not yet generated revenue and do not meet the CCPA's other jurisdictional tests, we do not yet meet the applicable threshold for the CCPA to apply to our business. If our business becomes subject to CCPA in the future, it could increase our compliance costs and potential liability. Similar laws have been proposed or passed in more than half of the states in the U.S. and in the U.S. Congress. Furthermore, all fifty U.S. states, the District of Columbia, Puerto Rico, and other U.S. territories have enacted data breach notification laws that require, among other things, notifications to state governments and/or the affected individuals in the event of a data breach, which differ from one another and impose significant compliance burden. As such, we will need to review periodically our operations in comparison to developments in such laws. Achieving and sustaining compliance with applicable international, federal and state privacy, security, and breach reporting laws may prove time-consuming and costly.

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 United States or in numerous foreign jurisdictions. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter.

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

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 U.S. Patent and Trademark Office (“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 U.S. 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 U.S. 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 U.S. patent, there is no assurance that a court would invalidate the claims of any such U.S. patent.

Parties making claims against us may obtain injunctive or other equitable relief. 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, 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 workforce reduction and portfolio prioritization announced in February 2024 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
In February 2024, we announced a workforce reduction of approximately 45% in connection with a prioritization of our portfolio and cost savings plan to focus on our clinical assets. We cannot guarantee that we will not undertake additional workforce reductions or restructuring activities in the future. Our updated operating plan may be disruptive to our operations and our workforce reductions may result in unanticipated consequences, including increased employee attrition, difficulties executing our day-to-day operations and reduced employee morale. In addition, there could be unforeseen expenses associated with our updated plan, and we could incur unanticipated charges or liabilities. As a result, we may not realize the expected cost savings or other benefits of such actions, which could have an adverse effect on our business, operating results and financial condition.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.
We are highly dependent on the expertise of the principal members of our management, scientific, and clinical teams. Our scientific and clinical development personnel have extensive experience developing and implementing novel clinical trial designs and successfully conducting clinical trials in never-before treated patient populations. If we lose one or more of our executive officers or key employees, our ability to execute our programs and implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the

limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully.

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

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

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

If employees who were not impacted by the workforce reduction seek alternate employment, we may have to increase reliance on external support to advance our operations. Any workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

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 system failure or accident to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials, or the loss of other proprietary data, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We are aware that a third party accessed the computer systems of one of our contractors and while we believe that such access did not result in loss of our proprietary data or disrupt our operations, we or our contractors may be subject to attacks in the future that could harm our business. Likewise, we currently rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, and the development of our product candidates could be delayed.

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

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals. In the ordinary course of our business, we and third parties with which we have relationships will

continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions.

Several proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors, or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored therein could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay the clinical development of our product candidates.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.
If a market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors.
Shares of our common stock were offered in our IPO in July 2021 at a price of $13.00 per share and between the date of our IPO and November 4, 2024, the closing price per share of our common stock has ranged from as low as $0.99 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;
- 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. 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 November 4, 2024, we have 41,487,586 shares of common stock outstanding. All of these shares may be resold in the public market immediately, unless held by our affiliates who are subject to volume limitations under Rule 144. As of November 4, 2024, we also have pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock outstanding. We may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which

percentage may be increased or decreased at the holder's election upon 61 days' notice to us subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99%.

Moreover, as of September 30, 2024, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On May 9, 2023, we registered an aggregate of 12,351,600 shares of common stock held by holders with registration rights, for resale, pursuant to a registration statement on Form S-3. In addition, we have entered into the Sales Agreement with Cowen to offer and sell shares of our common stock having an aggregate offering price of up to $100,000,000, from time to time, through an at-the-market offering program. We also registered an aggregate of 11,821,245 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 34% of our outstanding common stock as of November 4, 2024. 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, 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. On March 27, 2020, former President Trump signed into law the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. There also may be technical corrections legislation or other legislative changes proposed with respect to the TCJA and CARES Act, the effects of which cannot be predicted and may be adverse to us or our stockholders. Additionally, the IRA was enacted in August 2022.

Among other things, the IRA implemented a one percent (1%) excise tax on certain repurchases (including redemptions) of stock by publicly traded domestic corporations, and a corporate alternative minimum tax of fifteen percent (15%) on book income of certain large corporations. Future changes in tax laws could have a material adverse effect on our business, cash flows, financial condition or results of operations. In particular, proposed tax legislation could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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 United States may also impact our operations or affect global markets, such as the recent invasion of Ukraine by Russia and the Israel-Hamas war. While we do not currently conduct clinical trials in the Ukraine, Russia, or the Middle East, we cannot be certain what the overall impact of these events will be on our business or on the business of any of our third-party partners, including our contract research organizations, contract manufacturers or other partners. The impact of these events could also expand into other markets where we do business. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which current geopolitical tensions, the economic climate and the financial market conditions could adversely impact our business.

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

As a public company, we have incurred, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq 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 efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty

regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

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

(a)
Except as disclosed in our previously filed current reports on Form 8-K, the Company has not issued equity securities of the Company on an unregistered basis during the quarter ended September 30, 2024.

(b)
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 our 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.

Given our recent decision to prioritize our portfolio and reduce our expenses, we intend to use any remaining proceeds from our IPO primarily to support the development of RLYB212, working capital needs and general corporate purposes in support of the RLYB212 development program.

Item 5. Other Information

Director and Officer Trading Arrangements

During our quarter ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act, as amended) entered into, modified (as to amount, price or timing of trades) or terminated (i) contracts, instructions or written plans for the purchase or sale of our securities that are intended to satisfy the conditions specified in Rule 10b5-1(c) under the Exchange Act for an affirmative defense against liability for trading in securities on the basis of material nonpublic information or (ii) non-Rule 10b5-1 trading arrangements (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description
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.

\# The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.

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: November 7, 2024

By: /s/ Stephen Uden

Stephen Uden, M.D.

Chief Executive Officer, President and Director (Principal Executive Officer)

Date: November 7, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber

Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)

Exhibit 31.1

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

I, Stephen Uden, certify that:

1. I have reviewed this 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: November 7, 2024

By: /s/ Stephen Uden

Stephen Uden M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Jonathan I. Lieber, certify that:

1. I have reviewed this 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: November 7, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending September 30, 2024 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: November 7, 2024

By: /s/ Stephen Uden

Stephen Uden, M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending September 30, 2024 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: November 7, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)