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 March 31, 2026
OR

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

For the transition period from _____ to _____
Commission File Number: 001-40693

RALLYBIO CORPORATION
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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 May 8, 2026, the registrant had 5,298,137 shares of common stock, $0.0001 par value per share, outstanding.

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding timing of initiation and completion of our clinical trials for RLYB116, and related preparatory work, and the period during which the results of the trials will become available;
- the success, cost and timing of the clinical development of our product candidates, including RLYB116;
- the potential of our product candidates to treat certain target diseases;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to compete with companies currently marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including diseases of complement dysregulation, diseases of iron overload, immune platelet transfusion refractoriness ("PTR") and refractory antiphospholipid syndrome ("APS");
- our reliance on third parties to conduct our clinical trials;
- enhancements to the manufacturing process for RLYB116;
- our reliance on third parties to manufacture drug substance and drug product for use in our clinical trials;
- our ability to identify and advance through clinical development any additional product candidates;
- our ability to obtain and maintain regulatory designations allowing for priority review of our product candidates, and our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- the size and growth potential of the markets for RLYB116 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;

- our eligibility to receive milestone payments and royalties under our Membership Interest Purchase Agreement, dated July 8, 2025, with Recursion Pharmaceuticals, Inc. ("Recursion");

- the potential benefits of strategic collaboration agreements and arrangements and 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, if we continue to progress the development of our product candidates, we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability;

- If we continue to progress the development of our product candidates, we will require significant additional capital to fund our operations. If we continue to progress the development of our product candidates and fail to obtain necessary financing, we may not be able to complete the development or commercialization of RLYB116 or any other product candidate. Given our limited resources and access

to capital, we may decide to prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business;

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

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

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

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

- If we continue to progress the development of our product candidates, results of preclinical studies, clinical trials or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results;

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

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

- Our product candidates target rare diseases and conditions and if we continue to progress the development of our product candidates, the market opportunities for RLYB116 or any of our other product candidates, if approved, may be smaller than we anticipate. We must be able to successfully identify patients and capture a significant market share to achieve profitability and growth;

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

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

- If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected which may also impact the value of any potential contingent value right ("CVR").

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

RALLYBIO CORPORATION

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share amounts)	MARCH 31, 2026	DECEMBER 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 41,299	$ 31,374
Marketable securities	5,496	23,362
Prepaid expenses and other current assets	6,695	6,517
Total current assets	53,490	61,253
Property and equipment, net	20	23
Operating lease right-of-use assets	152	175
Other assets, noncurrent	810	810
Total assets	$ 54,472	$ 62,261
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 940	$ 126
Accrued expenses	3,101	3,791
Operating lease liabilities	99	94
Deferred revenue	—	212
Total current liabilities	4,140	4,223
Operating lease liabilities, noncurrent	55	82
Total liabilities	4,195	4,305
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized as of March 31, 2026 and December 31, 2025; and 5,290,236 and 5,283,321 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	4	4
Preferred stock, $0.0001 par value per share; 50,000,000 shares authorized as of March 31, 2026 and December 31, 2025; no shares issued or outstanding as of March 31, 2026 and December 31, 2025	—	—
Additional paid-in capital	360,548	359,932
Accumulated other comprehensive gain	1	18
Accumulated deficit	(310,276)	(301,998)
Total stockholders' equity	50,277	57,956
Total liabilities and stockholders' equity	$ 54,472	$ 62,261

See accompanying notes to the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	FOR THE THREE MONTHS ENDED MARCH 31,	
(in thousands, except share and per share amounts)	**2026**	**2025**
Revenue:		
Collaboration and license revenue	$ 212	$ 212
Total revenue	212	212
Operating expenses:		
Research and development	2,871	5,725
General and administrative	6,074	4,157
Total operating expenses	8,945	9,882
Loss from operations	(8,733)	(9,670)
Other income:		
Interest income	201	644
Other income	254	174
Total other income, net	455	818
Loss before equity in losses of joint venture	(8,278)	(8,852)
Loss on investment in joint venture	—	587
Net loss	$ (8,278)	$ (9,439)
Net loss per common share, basic and diluted	$ (1.46)	$ (1.69)
Weighted-average common shares outstanding, basic and diluted	5,688,584	5,597,528
Other comprehensive loss:		
Net unrealized loss on marketable securities	(17)	(21)
Other comprehensive loss	(17)	(21)
Comprehensive loss	$ (8,295)	$ (9,460)

See accompanying notes to the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

FOR THE THREE MONTHS ENDED MARCH 31, 2026 AND 2025	COMMON		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	STOCKHOLDERS' EQUITY
(in thousands, except share amounts)	**SHARES**	**AMOUNT**				
December 31, 2024	5,188,743	$ 4	$ 354,602	$ (293,020)	$ 68	$ 61,654
Share-based compensation	—	—	1,879	—	—	1,879
Issuance of common stock under the stock award plan	12,736	—	—	—	—	—
Net loss	—	—	—	(9,439)	—	(9,439)
Other comprehensive loss	—	—	—	—	(21)	(21)
Balance, March 31, 2025	5,201,479	$ 4	$ 356,481	$ (302,459)	$ 47	$ 54,073
December 31, 2025	5,283,321	$ 4	$ 359,932	$ (301,998)	$ 18	$ 57,956
Share-based compensation	—	—	613	—	—	613
Issuance of common stock under the stock award plan	6,354	—	—	—	—	—
Issuance of common stock from exercise of stock options	561	—	3	—	—	3
Net loss	—	—	—	(8,278)	—	(8,278)
Other comprehensive loss	—	—	—	—	(17)	(17)
Balance, March 31, 2026	5,290,236	$ 4	$ 360,548	$ (310,276)	$ 1	$ 50,277

See accompanying notes to the condensed consolidated financial statements

RALLYBIO CORPORATION

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)	FOR THE THREE MONTHS ENDED MARCH 31, 2026	2025
Cash Flows Used in Operating Activities:		
Net loss	$ (8,278)	$ (9,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3	28
Net accretion of discounts/premiums on debt securities	(51)	(210)
Share-based compensation	613	1,879
Loss on investment in joint venture	—	587
Changes in operating assets and liabilities:		
Prepaid expenses, operating lease right-of-use assets and other current assets	(155)	(506)
Accounts payable	814	122
Accrued expenses and operating lease liabilities	(712)	(2,454)
Deferred revenue	(212)	(212)
Net cash used in operating activities	(7,978)	(10,205)
Cash Flows Provided by Investing Activities:		
Purchases of marketable securities	—	(5,919)
Proceeds from maturities of marketable securities	17,900	18,000
Investment in joint venture	—	(1,000)
Net cash provided by investing activities	17,900	11,081
Cash Flows Provided by Financing Activities:		
Proceeds from the issuance of common stock from exercise of stock options	3	—
Net cash provided by financing activities	3	—
Net increase in cash and cash equivalents	9,925	876
Cash and cash equivalents — beginning of period	31,374	13,903
Cash and cash equivalents — end of period	$ 41,299	$ 14,779

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

On March 1, 2026, Rallybio entered into an Agreement and Plan of Merger and Reorganization with Candid Therapeutics, Inc. (“Candid”) (the “Merger Agreement”) pursuant to which the parties intended to undertake a business combination (the “Merger”).

On May 3, 2026, Candid terminated the Merger Agreement concurrently with entering into a Permitted Alternative Agreement (as defined in the Merger Agreement) with UCB S.A. (“UCB”). As a result of the termination of the Merger Agreement, Rallybio was paid on May 4, 2026 a $50.0 million Parent Termination Fee (as defined in the Merger Agreement) and was reimbursed $0.4 million for certain expenses.

The Company had cash, cash equivalents and marketable securities of $46.8 million as of March 31, 2026. 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 March 31, 2026 will be sufficient to fund any of its product candidates through regulatory approval, and it will need to raise substantial additional capital to complete the development and commercialization of its product candidates, if approved. Rallybio may satisfy its future cash needs through the sale of equity securities, debt financings, corporate collaborations or license agreements, working capital lines of credit, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

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.

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 Rallybio's Annual Report on Form 10-K for the year ended December 31, 2025 (our "Annual Report"). The Company's 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 months ended March 31, 2026, unless otherwise noted below, which could be expected to materially impact the Company's unaudited condensed consolidated financial statements.

Significant Accounting Policies —

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

The Company periodically reviews the carrying value of the contingent consideration when impairment indicators arise and records an impairment loss if the carrying amount materially exceeds the reassessed fair value. Increases in the carrying value are recognized only when contingent gains are realized. Since the contingent payments are tied to Phase 1 clinical study milestones and future royalty payments, the Company believes the likelihood of timely payment by Recursion is uncertain.

Recently Issued Accounting Pronouncements—In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): *Disaggregation of Income Statement Expenses (*"ASU 2024-03"). This ASU requires public entities to disclose additional transparency on certain costs and expenses. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company has chosen not to early adopt this standard and is currently evaluating the potential impact of adopting this standard on its 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 March 31, 2026 and December 31, 2025 was as follows:

		MARCH 31, 2026			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Cash and cash equivalents	Level 1	$ 16,383	$ —	$ —	$ 16,383
U.S. treasury securities	Level 1	5,495	1	—	5,496
		$ 21,878	$ 1	$ —	$ 21,879

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

The fair values of marketable securities by classification in the condensed consolidated balance sheets as of March 31, 2026 and December 31, 2025 was as follows:

(in thousands)	MARCH 31, 2026	DECEMBER 31, 2025
Cash and cash equivalents	$ 16,383	$ 7,193
Marketable securities	5,496	23,362
	$ 21,879	$ 30,555

The fair values of available-for-sale debt securities as of March 31, 2026 and December 31, 2025, by contractual maturity, are summarized as follows:

(in thousands)	MARCH 31, 2026	DECEMBER 31, 2025
Due in one year or less	$ 21,879	$ 30,555
Due after one year through two years	—	—
	$ 21,879	$ 30,555

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2025 was $0.7 million. There was no aggregate fair value of available-for-sale debt securities in an unrealized loss position as of March 31, 2026. As of March 31, 2026, the Company did not have any investments in a continuous unrealized loss position for more than twelve months. As of March 31, 2026, the Company believes that the cost basis of its available-for-sale debt securities is recoverable. No allowance for credit loss was recorded as of March 31, 2026 and December 31, 2025.

4. BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets —
Prepaid expenses and other current assets consisted of the following as of March 31, 2026 and December 31, 2025:

(in thousands)	MARCH 31, 2026	DECEMBER 31, 2025
Research and development	$ 595	$ 3,372
Insurance	231	409
Other prepaids	135	219
Other current assets	5,734	2,517
	$ 6,695	$ 6,517

Other current assets consists of approximately $3.4 million of accounts receivable related to clinical development costs expected to be returned to the Company in the second quarter of 2026, approximately $2.2 million related to a contingent payment receivable tied to a Phase 1 clinical study milestone in connection with the JV Sale, approximately $0.1 million of interest income and other current assets.

Accrued Expenses —
Accrued expenses consisted of the following as of March 31, 2026 and December 31, 2025:

(in thousands)	MARCH 31, 2026	DECEMBER 31, 2025
Compensation and related expenses	$ 1,407	$ 2,334
Professional fees	1,396	1,039
Research and development	94	394
Other accrued expenses	204	24
	$ 3,101	$ 3,791

5. STOCKHOLDERS' EQUITY

Common Stock
In April 2024, the Company entered into a securities purchase agreement (the "JJDC Securities Purchase Agreement") with Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"), pursuant to which the Company sold to JJDC, in an unregistered offering, 454,545 shares of its common stock, at a price of $14.56 per share, which represented 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 March 31, 2026 and December 31, 2025, of which 5,290,236 and 5,283,321 shares were issued and outstanding as of March 31, 2026 and December 31, 2025, respectively.

Preferred Stock
The Company had 50,000,000 shares of preferred stock authorized as of March 31, 2026 and December 31, 2025, of which no shares were issued or outstanding as of March 31, 2026 and December 31, 2025.

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

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

The Company's pre-funded warrant is a freestanding instrument that does not meet the definition of a liability pursuant to ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and does not meet the definition of a derivative pursuant to ASC 815, *Derivatives and Hedging* ("ASC 815"). The pre-funded warrant is indexed to the Company's common stock and meets all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the pre-funded warrant was classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. All of the pre-funded warrants related to the November 2022 follow-on offering remain outstanding and unexercised as of March 31, 2026.

Share-based Compensation
Share-based compensation is comprised of the Company's stock options, restricted stock awards, restricted stock units and shares issued pursuant to the employee stock purchase plan, and is classified in the condensed

consolidated statements of operations and comprehensive loss for the three months ended March 31, 2026 and 2025 was as follows:

	FOR THE THREE MONTHS ENDED MARCH 31,	
(in thousands)	2026	2025
Research and development	$ 184	$ 810
General and administrative	429	1,069
	$ 613	$ 1,879

2021 Equity Incentive Plan

In 2021, the board of directors adopted the Rallybio Corporation 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan initially reserved 680,043 shares of the Company's common stock that have been issued in respect of outstanding equity awards granted prior to the 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, 2026 and January 1, 2025, the 2021 Plan share pool was automatically increased by 264,166 and 259,438 shares, respectively. As of March 31, 2026, the total number of shares of the Company's common stock that were issuable under the 2021 Plan was 1,514,824 shares, of which 834,331 shares remained available for future issuance.

The following table summarizes stock option activity for the three months ended March 31, 2026:

Stock Options	Number of Option Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding stock options at December 31, 2025	628,280	$ 43.42	7.6	$ 89
Granted	32,360	$ 4.45		
Forfeited	(11,404)	$ 15.70		
Expired	(1,281)	$ 88.75		
Exercised	(561)	$ 6.08		
Outstanding stock options at March 31, 2026	647,394	$ 41.90	6.2	$ 749
Exercisable stock options at March 31, 2026	427,642	$ 56.52	5.6	$ 180

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock. Stock options outstanding with an exercise price below the closing price as of March 31, 2026 had an intrinsic value of approximately $749 thousand. Stock options outstanding and exercisable with an exercise price below the closing price as of March 31, 2026 had an intrinsic value of $180 thousand. These values are based on a common stock fair value of $8.97 per share, which was the closing price of the Company's common stock on March 31, 2026. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the three months ended March 31, 2026 and 2025 was $3.60 per share and $5.36 per share, respectively. As of March 31, 2026, there was unrecognized share-based compensation expense related to nonvested stock options of $2.2 million, which the Company expects to recognize over a weighted-average period of approximately 1.6 years. As of March 31, 2026, in connection with the consummation of the now-terminated proposed Merger, all nonvested stock options were expected to vest and the remaining expense would have been recognized.

The fair value of the stock options granted during the three months ended March 31, 2026 and 2025 was determined using the Black-Scholes option pricing model with the following assumptions:

	FOR THE THREE MONTHS ENDED MARCH 31,	
	2026	2025
Expected volatility	109.21%	91.88% - 119.61%
Expected term (years)	5.25	5.27 - 6.02
Risk free interest rate	3.68%	4.36% - 4.39%
Expected dividend yield	—	—
Exercise price	$4.45	$6.08 - $7.60

A summary of the status of the Company's nonvested restricted common stock units at March 31, 2026 and changes during the three months ended March 31, 2026 was as follows:

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested restricted stock units at December 31, 2025	38,603	$ 9.60
Granted	5,000	$ 4.45
Forfeited	(4,150)	$ 2.40
Vested	(6,354)	$ 7.79
Nonvested restricted stock units at March 31, 2026	33,099	$ 10.07

As of March 31, 2026, there was unrecognized share-based compensation expense related to nonvested restricted stock units of $0.2 million, which the Company expects to recognize over a weighted-average period of approximately 2.0 years. As of March 31, 2026, in connection with the consummation of the now-terminated proposed Merger, all nonvested restricted stock units were expected to vest and the remaining expense would have been recognized.

2021 Employee Stock Purchase Plan

In connection with the Company's IPO, the board of directors adopted the Rallybio Corporation 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which initially reserved 36,415 shares of the Company's common stock for future issuances under this plan. The share pool will automatically increase on January 1st of each year from 2022 to 2031, by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date, (ii) 72,831 shares of the Company's common stock and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. The 2021 ESPP share pool did not increase on January 1, 2026 or January 1, 2025. As of March 31, 2026, the total number of shares of the Company's common stock available for future issuance under the 2021 ESPP was 94,281 shares. During the three months ended March 31, 2026 and 2025, the Company did not issue any of the Company's common stock under the 2021 ESPP.

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

6. INVESTMENT IN JOINT VENTURE

In July 2025, the Company entered into a Membership Interest Purchase Agreement (the "ENPP1 Purchase Agreement") to sell its interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with HPP, to Recursion Exscientia Ventures I, Inc, an indirect wholly-owned subsidiary of Recursion ("Buyer"). In connection with the JV Sale, the Company received compensation in the form of Recursion common stock (which is a non-cash investing activity). The Company subsequently sold the Recursion common stock for cash proceeds of $20.0 million in the third quarter of 2025 which included $7.5 million from an upfront

payment and $12.5 million from a milestone payment related to the initiation of additional preclinical studies. The Company is eligible to receive a $5.0 million milestone cash payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the ENPP1 Purchase Agreement and low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed by RE Ventures I, LLC, a limited liability company ("REV-I"). The Company may also be eligible to receive certain payments in the event of Recursion's sale of the REV102 program.

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

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

Prior to the JV Sale, the Company, through one of its wholly-owned subsidiaries, had a 50% interest of the joint venture entity, REV-I. For the three months ended March 31, 2026, the Company did not fund REV-I due to the JV Sale. For the three months ended March 31, 2025, the Company funded $1.0 million, associated with the Company's commitment and its share of REV-I development costs. The Company did not provide any additional financial support outside of capital contributions to REV-I during the three months ended March 31, 2026 and 2025. However, in connection with the joint venture, the Company provided certain scientific and finance and accounting related support which was reimbursed by REV-I to the Company and included in other income on the condensed consolidated statements of operations and comprehensive loss. For the three months ended March 31, 2026 the Company did not provide such support due to the JV Sale. For the three months ended March 31, 2025, the Company recorded $0.2 million related to such support. Prior to the JV Sale, the Company held a 50% interest in the joint venture and based on management's analysis, the Company was not the primary beneficiary of REV-I and accordingly, the entity was not consolidated in the Company's condensed consolidated financial statements.

For the three months ended March 31, 2026, the Company did not have allocable share of REV-I losses due to the JV Sale. For the three months ended March 31, 2025, the Company recorded its allocable share of REV-I's losses which totaled $0.6 million. 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, there was no carrying value remaining of the REV-I investment as of March 31, 2026 and December 31, 2025.

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 the Company upon written notice. Payments that may be due upon cancellation consist of payments for services provided or expenses incurred prior to cancellation. As of March 31, 2026 and December 31, 2025, 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 months ended March 31, 2026 and 2025 was calculated as follows:

(in thousands except share and per share amounts)	FOR THE THREE MONTHS ENDED MARCH 31, 2026	2025
Net loss	$ (8,278)	$ (9,439)
Weighted-average number of common shares outstanding, basic and diluted	5,688,584	5,597,528
Net loss per common share, basic and diluted	$ (1.46)	$ (1.69)

Basic net loss per share of common stock is based on the weighted-average number of shares of common stock outstanding during the period. Pre-funded warrants to purchase 416,673 shares of common stock that were issued in connection with the November 2022 follow-on offering are included in the weighted-average number of common shares outstanding for the three months ended March 31, 2026 and 2025. The weighted- average number of common shares outstanding diluted for the three months ended March 31, 2026 and 2025 excluded approximately 0.7 million and 0.9 million stock options and nonvested restricted stock awards and units, respectively, which were not dilutive.

9. SEGMENTS

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

The following table summarizes the information about reported segment revenues and significant segment expenses presented on the Company's condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2026 and 2025:

(in thousands)	FOR THE THREE MONTHS ENDED MARCH 31, 2026	2025
Revenue	$ 212	$ 212
Less:		
Research and development:		
RLYB212	56	2,438
RLYB116	396	619
Other program candidates	2	(163)
Personnel expenses (including share-based compensation)	2,280	2,589
Other expenses	137	242
General and administrative, excluding personnel expenses	4,223	1,525
General and administrative, personnel expenses (including share-based compensation)	1,851	2,632
Other segment items*	(455)	(231)
Segment net loss	$ (8,278)	$ (9,439)

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

10. RESTRUCTURING AND SEVERANCE

In connection with entering into the Merger Agreement and the potential Merger, the Company incurred severance charges of approximately $2.3 million of which $1.6 million was included in research and development expenses and $0.7 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 Merger Agreement were cash-based expenditures related primarily to severance and benefit payments. The Company recognized all such charges during the first quarter of 2026, with such amounts reflected in the condensed consolidated statements of operations and comprehensive loss. The accrued severance liability is included in accrued expenses in the condensed consolidated balance sheets as of March 31, 2026.

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

As part of this effort, the Company eliminated approximately 40% of its positions. As a result of these actions, the Company incurred charges of approximately $1.7 million of which $1.2 million was included in research and development expenses and $0.5 million was included in general and administrative expenses, with such amounts reflected in the condensed consolidated statements of operations and comprehensive loss. The charges related to the workforce reduction were cash-based expenditures related primarily to severance and benefit payments. The Company recognized all such charges during the second quarter of 2025, with such amounts reflected in the condensed consolidated statements of operations and comprehensive loss. The accrued restructuring liability is included in accrued expenses in the condensed consolidated balance sheets as of March 31, 2026.

All restructuring and severance payments related to the terminated Merger are expected to be paid within the next 12 months.

The following table summarizes the restructuring accrual activity as of March 31, 2026:

(in thousands)	MARCH 31, 2026
Beginning accrued severance as of January 1, 2026	$ 523
Severance incurred during the period	2,302
Severance paid and adjustments made during the period	(1,449)
Ending accrued severance as of March 31, 2026	$ 1,376

11. COLLABORATION AND LICENSE AGREEMENTS`

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

In April 2025, the Company announced that RLYB212 Phase 2 PK results did not achieve target concentrations, including the minimum target concentration required for efficacy, and that the Company would discontinue its RLYB212 program for the prevention of FNAIT.

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

The Company evaluated the agreement and determined it was within the scope of ASC 606, *Revenue Recognition* ("ASC 606"). The Company determined there were performance obligations as follows:

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

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

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

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

The Company recognized revenue of $0.2 million for both the three months ended March 31, 2026 and 2025, 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. As of March 31, 2026, all revenue was recognized due to the performance obligations being satisfied. On April 9, 2026, the J&J Collaboration Agreement terminated upon completion of the initial term of the agreement.

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

12. SUBSEQUENT EVENTS

On March 1, 2026, Rallybio entered into an Agreement and Plan of Merger and Reorganization with Candid pursuant to which the parties intended to undertake a business combination.

On May 3, 2026, Candid terminated the Merger Agreement concurrently with entering into a Permitted Alternative Agreement (as defined in the Merger Agreement) with UCB. As a result of the termination of the Merger Agreement, Rallybio was paid on May 4, 2026 a $50.0 million Parent Termination Fee (as defined in the Merger Agreement) and was reimbursed $0.4 million for certain expenses.

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, 2025 (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. Our lead program, RLYB116, is a differentiated complement component 5 ("C5") inhibitor with the potential to treat diseases of complement dysregulation. In addition, RLYB332, a long-acting matriptase-2 ("MTP-2") antibody for the treatment of diseases of iron overload is currently in preclinical development.

On March 1, 2026, Rallybio Corporation and subsidiaries ("Rallybio", the "Company", "we", "our", or "us") entered into an Agreement and Plan of Merger and Reorganization with Candid Therapeutics, Inc ("Candid") (the "Merger Agreement") pursuant to which the parties intended to undertake a business combination (the "Merger").

On May 3, 2026, Candid terminated the Merger Agreement concurrently with entering into a Permitted Alternative Agreement (as defined in the Merger Agreement) with UCB S.A. ("UCB"). As a result of the termination of the Merger Agreement, we were paid on May 4, 2026 a $50.0 million Parent Termination Fee (as defined in the Merger Agreement) and were reimbursed $0.4 million for certain expenses.

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

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

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

Complement Dysregulation

RLYB116 is an innovative, once-weekly, small volume, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-related diseases. We have completed two Phase 1 clinical trials in healthy participants that included the study of RLYB116 as both a single-ascending dose and a multiple-ascending dose. After the first Phase 1 clinical trial, we completed manufacturing process enhancements that were designed to improve the tolerability of RLYB116. In 2025, we completed the confirmatory Phase 1 clinical trial evaluating the PK/PD properties of RLYB116. The confirmatory trial achieved its two key objectives

including: a significant improvement in the tolerability of RLYB116 and demonstration of complete and sustained inhibition of terminal complement. These results, which we reported in the first quarter of 2026, support the study of RLYB116 as a potential best-in-class therapeutic for multiple complement mediated diseases.

Hematological Disorders
In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. In 2024, we re-engineered RLYB331 to extend its half-life and completed non-clinical studies that demonstrated favorable tolerability, dose-dependent PK, and sustained PD effects with RLYB332, a long-acting version of RLYB331. These findings, which were presented in a poster at the 66th annual meeting of the American Society of Hematology, support the continued development of RLYB332 as a potentially best-in-class therapeutic for treating diseases of iron overload.

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

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

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

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

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

As of March 31, 2026, we had cash, cash equivalents and marketable securities of $46.8 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating

expenses and capital expenditure requirements for at least 12 months beyond the filing of this Quarterly Report on Form 10-Q. See "— Liquidity and Capital Resources."

We have incurred significant operating losses since inception, including net losses of $8.3 million and $9.4 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $310.3 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. There can be no assurances, however, that additional funding will be available on terms acceptable to us, or at all.

Components of Results of Operations

Revenue

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

We determined there were performance obligations as follows:

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

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

In April 2024, we also entered into the JJDC Securities Purchase Agreement. Under the terms of the JJDC Securities Purchase Agreement, JJDC made an equity investment purchasing 454,545 shares of common stock with a par value of $0.0001 per share for a share purchase price of $14.56 per share which includes a 10% premium for an aggregate purchase price of $6.6 million. The JJDC Securities Purchase Agreement contains provisions related to the registration of the shares and the restriction on the sale or transfer of the shares for a period of time. We determined the J&J Collaboration Agreement and JJDC Securities Purchase Agreement represented combined agreements. In accordance with Accounting Standards Codification 606, *Revenue Recognition* and Accounting Standards Codification Topic 820, *Fair Value Measurement*, total consideration of $1.2 million for the shares of common stock from the JJDC Securities Purchase Agreement, which represents the premium of $0.7 million and discount for lack of marketability of $0.5 million, has been allocated to revenue and will be recognized over the two-year expected performance period. As of March 31, 2026, all revenue was recognized due to the performance obligations being satisfied. On April 9, 2026, the J&J Collaboration Agreement terminated upon completion of the initial term of the agreement.

Operating Expenses

Research and Development Expenses

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

- external research and development expenses incurred under agreements with third parties, such as contract research organizations ("CROs") as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;

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

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

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

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

The successful development of any product candidate is highly uncertain. We will need to raise substantial additional capital in the future to fund the future development of our current programs. We intend to focus our near term research and development efforts on completing the ongoing activities and preparing our programs for a potential transaction or sale.

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

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

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table summarizes our results of operations:

(in thousands)	FOR THE THREE MONTHS ENDED MARCH 31, 2026	2025	CHANGE
Revenue:			
Collaboration and license revenue	$ 212	$ 212	$ —
Total revenue	212	212	—
Operating expenses:			
Research and development	2,871	5,725	(2,854)
General and administrative	6,074	4,157	1,917
Total operating expenses	8,945	9,882	(937)
Loss from operations	(8,733)	(9,670)	937
Total other income, net	455	818	(363)
Loss before equity in losses of joint venture	(8,278)	(8,852)	574
Loss on investment in joint venture	—	587	(587)
Net loss	$ (8,278)	$ (9,439)	$ 1,161

Revenue

Collaboration and license revenue was $0.2 million for both the three months ended March 31, 2026 and 2025.

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 MARCH 31, 2026	2025	CHANGE
Direct research and development by program			
RLYB212	$ 56	$ 2,438	$ (2,382)
RLYB116	396	619	(223)
Other program candidates	2	(163)	165
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	2,280	2,589	(309)
Other expenses	137	242	(105)
Total research and development expenses	$ 2,871	$ 5,725	$ (2,854)

Research and development expenses were $2.9 million for the three months ended March 31, 2026, compared to $5.7 million for the three months ended March 31, 2025. The decrease of $2.9 million in 2026 as compared to 2025 was primarily due to:

- a $2.4 million decrease in RLYB212 development costs, primarily related to a decrease in clinical development costs and other related development costs as a result of our discontinuation of the FNAIT program in April 2025;
- a $0.2 million decrease in RLYB116 development costs, primarily related to a decrease in manufacturing costs and other related development costs; and
- a $0.3 million decrease in personnel expenses, primarily related to lower ongoing headcount during the three months ended March 31, 2026 as compared to the same period in 2025, in

addition to a decrease in share-based compensation and the lack of any bonus accrual in 2026; offset by an increase in severance recognized in connection with the terminated Merger with Candid.

General and administrative expenses were $6.1 million for the three months ended March 31, 2026, compared to $4.2 million for the three months ended March 31, 2025. The increase of $1.9 million in 2026 as compared to 2025 was primarily due to:

- a $2.7 million increase primarily related to legal fees, professional fees and other related general and administrative expenses, the vast majority of which was incurred in connection with the terminated Merger with Candid.

This increase was partially offset by:

- a $0.8 million decrease in personnel expenses, primarily related to lower ongoing headcount during the three months ended March 31, 2026 as compared to the same period in 2025, in addition to a decrease in share-based compensation and the lack of any bonus accrual in 2026; offset by an increase in severance recognized in connection with the terminated Merger with Candid.

Total Other Income, Net
Total other income, net, for the three months ended March 31, 2026 was $0.5 million compared to $0.8 million for the three months ended March 31, 2025. The decrease in total other income of $0.4 million 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 was $0.6 million for the three months ended March 31, 2025. In July 2025, we sold our interest in REV102 to Recursion which resulted in no loss on investment in joint venture for the three months ended March 31, 2026.

Liquidity and Capital Resources

Sources of Liquidity

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

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

In August 2022, we filed a Registration Statement on Form S-3 (the “Shelf”) with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $300.0 million. The Shelf was declared effective on August 15, 2022. Pursuant to General Instruction I.B.6 to Form S-3 (“Instruction I.B.6”), a company with a public float of less than $75.0 million measured at certain time periods may not issue securities under Registration Statements on Form S-3 in excess of one-third of its public float in a 12-month period. We are subject to the limitations of Instruction I.B.6, which may limit the amount of funds we can raise using the Shelf or any other Registration Statement on Form S-3. In connection with the Shelf, we also simultaneously entered into a Sales Agreement with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) ("TD Cowen"), which was amended on March 13, 2025 (as amended, the "Sales Agreement"). In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $9.55 million from time to time at prices through TD Cowen acting as our agent. Pursuant to the Sales Agreement, sales of our common stock, if any, will be made in sales deemed to be “at the market offerings” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act").

Under the Sales Agreement, TD Cowen will be entitled to compensation equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of March 31, 2026, we had not sold any shares of common stock pursuant to the Sales Agreement.

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

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

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

In May 2026, we received a $50.0 million Parent Termination Fee in connection with the termination of the Merger Agreement.

As of March 31, 2026, we had $46.8 million of cash, cash equivalents and marketable securities.

Uses of Liquidity

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years. See "Contractual Obligations" below.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months beyond the filing of this Quarterly Report on Form 10-Q.

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.

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 THREE MONTHS ENDED MARCH 31,	
(in thousands)	**2026**	**2025**
Net cash used in operating activities	$ (7,978)	$ (10,205)
Net cash provided by investing activities	17,900	11,081
Net cash provided by financing activities	3	—
Net increase in cash and cash equivalents	$ 9,925	$ 876

Operating Activities
During the three months ended March 31, 2026, net cash used in operating activities was $8.0 million as compared to $10.2 million during the three months ended March 31, 2025. The decrease in net cash used in operating activities during the three months ended March 31, 2026 as compared to the three months ended March 31, 2025 was primarily related to a decrease in research and development activities; offset by an increase in general and administrative activities.

Investing Activities
Net cash provided by investing activities was $17.9 million during the three months ended March 31, 2026 as compared to $11.1 million of net cash provided by investing activities during the three months ended March 31, 2025. The increase of $6.8 million in net cash provided by investing activities was primarily related to proceeds of $17.9 million from maturities of highly-rated debt securities during the three months ended March 31, 2026, as compared to proceeds from maturities of highly-rated debt securities of $18.0 million, partially offset by purchases of highly-rated debt securities of $5.9 million during the three months ended March 31, 2025.

Financing Activities
Net cash provided by financing activities for the three months ended March 31, 2026 was $3 thousand, representing proceeds from the issuance of common stock from exercise of stock options. There were no financing activities during the three months ended March 31, 2025.

Contractual Obligations

There have been no other material changes in our contractual obligations and commitments during the three months ended March 31, 2026 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 the consolidated financial statements in 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 Jumpstart Our Business Startups Act of 212 (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 an EGC, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-Balance Sheet Arrangements

As of March 31, 2026 and December 31, 2025, 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 March 31, 2026. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC 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 judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2026, 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, if we continue to progress the development of our product candidates, we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a limited operating history. As a result, we are not profitable and we have incurred significant operating losses since inception, including net losses of $8.3 million and $9.4 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $310.3 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Since inception, we have devoted substantially all of our resources to raising capital, conducting discovery and research activities, acquiring product candidates, establishing and protecting our intellectual property, preparing for and conducting clinical trials, and establishing arrangements with third parties for the manufacture of our product candidates. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

If we continue to progress the development of our product candidates, we expect to incur significant additional operating losses in the foreseeable future as we advance our programs and operate our business. The costs of advancing product candidates through each clinical phase tend to increase substantially over the duration of the clinical development process. The total costs to advance a single product candidate to marketing approval in even a single jurisdiction are substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will increase substantially if and as we:

- plan for and conduct any future clinical trials for any of our product candidates, including the ongoing RLYB116 confirmatory clinical PK/PD trial;
- seek regulatory approvals for RLYB116 and any other product candidates;
- advance our discovery and preclinical development activities for our product candidates;
- discover and develop additional product candidates;

- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate clinical and commercial quantities of our product candidates; and
- establish a sales, marketing, and distribution infrastructure to commercialize our products, if approved.

We do not know when or whether we will become profitable. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates and to obtain the necessary regulatory approvals for their commercialization, which is subject to substantial additional risks and uncertainties, as described under "— Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval."

Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, the securing of clinical and commercial manufacturing supply, the building of a commercial organization, and substantial investment before we generate any revenue from product sales. As a result, if we continue to progress the development of our product candidates, we expect to continue to incur net losses and negative cash flows in the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through current or future collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we successfully commercialize RLYB116 or any of our other product candidates, we may continue to incur substantial research and development and other expenses to develop other current or future product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis or meet outside expectations for our profitability. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, execute our business plan or continue our operations.

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

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

If we continue to progress the development of our product candidates, we believe that our existing cash, cash equivalents and marketable securities as of March 31, 2026, will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months beyond the date of the filing of this Quarterly Report on Form 10-Q. This estimate and our expectation to advance the preclinical and clinical development of RLYB116 and any other product candidates are based on assumptions that may prove to be wrong, or we may be subject to changing circumstances. We could exhaust our available capital resources sooner than we expect. Our business is subject to numerous risks and uncertainties, and we may be unable to accurately estimate the actual amount of funds we will require for development and commercialization of our product candidates. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

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

If we continue to progress the development of our product candidates, we will require significant additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements, strategic alliances and licensing arrangements or other sources. Depending on our business performance, the economic climate and market conditions, we may be unable to raise additional funds when needed on favorable terms, or at all. Furthermore, pursuant to Instruction I.B.6, a company with a public float of less than $75 million measured at certain time periods may not issue securities under Registration Statements on Form S-3 in excess of one-third of its public float in a 12-month period. For purposes of the prior sentence, “public float” means the aggregate market value of a company’s shares held by non-affiliates. We are subject to the limitations of Instruction I.B.6 which may limit the amount of funds we can raise using Registration Statements on Form S-3. Moreover, uncertain geopolitical events, such as the war in Ukraine and conflict in Israel, and uncertain global economic conditions, including as a result of changes in tariffs and other trade restrictions, have impacted the global economy, and a severe or prolonged economic downturn could result in a variety of challenges for our business, including disruptions in the financial markets, which could adversely impact our ability to raise additional capital when needed or on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may need to significantly delay, scale back or discontinue the development of one or more of our product candidates or the commercialization of any product that may be approved for marketing, or we could be forced to discontinue operations. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Because we have limited financial resources, we have focused and may continue to focus on a limited set of research programs and product candidates and for a limited set of indications. We may forego or delay pursuit

of opportunities with certain other product candidates or for other indications that could have greater commercial potential or a greater likelihood of success. Our capital allocation decisions may cause us to fail to realize value from, or advance, viable commercial products or profitable market opportunities.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates.
If we continue to progress the development of our product candidates, until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
Rallybio was founded in January 2018 and our operations to date have been limited primarily to research and development activities, and raising capital. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

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

- variations in the level of expense related to any ongoing development of our product candidates or research pipeline;

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

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

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

We have incurred substantial NOLs during our history. To the extent that we continue to generate taxable losses, unused losses will carry forward and can be used to offset future taxable income, if any, until such unused losses expire. NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration. Federal NOLs generated in taxable years beginning after December 31, 2017 generally may not be carried back to prior taxable years. The deduction for NOLs arising in taxable years beginning after December 31, 2017 is generally limited to 80% of current year taxable income. We also have substantial federal and state research and development and other tax credit carryforwards. These tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, (the “Code”), a corporation that undergoes an “ownership change” is subject to limitations on its ability to use its pre-change NOLs and tax credit

carryforwards to offset future taxable income. Some of our historical NOLs may be subject to annual limitations on our ability to use them due to prior ownership changes. Additionally, we may experience such ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we undergo an ownership change, our ability to use our NOLs and income tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing, Marketing Approval and Commercialization

We are heavily dependent on the success of RLYB116, which is in early-stage clinical development. If we continue to progress the development of our product candidates, and we are not able to develop, obtain marketing approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed. Our lead program, RLYB116, is in early-stage clinical development and we do not currently have any products that generate revenues or any other sources of revenue. To date, we have invested a significant portion of our efforts and financial resources in the development of RLYB212 and RLYB116. If we continue to progress the development of our product candidates, our future success is substantially dependent on our ability to successfully complete preclinical and clinical development for, obtain marketing approval for, and successfully commercialize, RLYB116 and our other product candidates, which may never occur. None of our product candidates are approved for commercial sale and we may never be able to develop a marketable product.

Before obtaining marketing approvals for the commercial sale of our product candidates, we must demonstrate the safety and efficacy of our product candidates for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Failure can occur at any time during the preclinical study and clinical trial processes. Because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products. If we continue to progress the development of our product candidates, our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. Ongoing and future preclinical studies and clinical trials of our product candidates may not show sufficient safety or efficacy or be of sufficient quality to obtain or maintain marketing approvals. For example, PK data from the Phase 2 clinical trial for RLYB212 demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. There can be no assurance that any of our product candidates, even if approved, will prove to be commercially viable therapeutics.

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

If we continue to progress the development of our product candidates, the success of our product candidates will depend on several factors, including the following:

- successful and timely initiation of preclinical studies, and successful and timely initiation of, enrollment in, and completion of our clinical trials with results that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations within the timeframes we have projected;

- regulatory grants of authorization to proceed under investigational new drug applications or clinical trial authorization (“CTAs”) such that we can commence planned or future clinical trials of our product candidates;

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;

- our ability to successfully utilize certain delivery systems, such as pre-filled syringes ("PFSs"), pen-injectors and/or autoinjectors, for certain of our product candidates and to obtain marketing approval of any such drug/device combination product;
- the outcome, timing, and cost of meeting regulatory requirements, including any post-marketing commitments, established by the FDA, EMA and other comparable foreign regulatory authorities;
- establishing commercially viable arrangements with third-party manufacturers for clinical and commercial supply;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution capabilities, whether alone or through a collaboration, to support commercialization of our product candidates, if and when approved;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively differentiating and competing with other therapies approved and/or used for the same indications as our product candidates, particularly RLYB116;
- obtaining and maintaining third-party coverage and reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining an acceptable safety profile of the product candidates following approval.

If we do not successfully address one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to commercialize our product candidates, which would materially harm our business. Due to the uncertain and time-consuming clinical development and marketing approval process, we may not successfully develop any of our product candidates and may choose to discontinue the development of any of our product candidates prior to receiving marketing approval. If we discontinue development of a product candidate, we will not receive anticipated revenues from that product candidate and we may not receive any return on our investment in that product candidate. We may discontinue a product candidate for clinical reasons if it does not prove to be safe and effective for its targeted indications, or if such product candidates do not achieve the necessary efficacy at tolerated doses required for patient benefit. For example, we discontinued RLYB212 development based on PK data from the Phase 2 clinical trial that demonstrated an inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. In addition, there may be important facts about the safety, efficacy and risk versus benefit of our product candidates that are not known to us at this time. Any unexpected safety events or our failure to generate sufficient data in our clinical trials to demonstrate efficacy may cause a product candidate to fail clinical development. Furthermore, even if that product candidate meets its safety and efficacy endpoints, we may discontinue its development for various reasons, such as changes in the competitive environment or the standard of care and the prioritization of our resources.

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

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

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

If we continue to progress the development of our product candidates, we may experience events that could delay or prevent our ability to complete current clinical trials or initiate and complete new trials, any of which may impact our product development timelines, result in increased costs, affect our ability to obtain marketing approval according to our plans, and delay commercialization of our product candidates. These events include, but are not limited to:

- the FDA, EMA or other comparable foreign regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to commence a trial;
- delays in receiving or denial by regulatory agencies of permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or placement of a clinical trial on hold;
- negative results from our non-clinical trials or clinical trials;
- challenges, delays and cost involved in identifying, recruiting and retaining suitable participants and clinical trial sites in sufficient numbers to participate in clinical trials;
- delays in reaching an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining an independent 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 practices ("GCP") requirements and trial protocol;
- inadequate quantity or quality of product candidate or other materials necessary to conduct clinical trials, for example as a result of delays in defining and implementing the manufacturing process for materials used in clinical trials or for the manufacture of larger quantities or other delays or issues arising in the manufacturing of sufficient supply of finished drug product;
- lack of adequate funding to continue a clinical trial, including as a result of unanticipated costs or increases in costs of clinical trials;

- occurrence of serious adverse events including unexpected serious adverse events, associated with the product candidate or reports from non-clinical or clinical testing of our own or competing therapies that raise safety or efficacy concerns, or delays or failures in addressing patient safety concerns that arise during the course of a trial;

- changes in regulatory requirements and guidance that require changes to planned or ongoing preclinical and clinical studies, or the conduct of additional studies; and

- difficulties recruiting and retaining employees, consultants or contractors with the required level of expertise.

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

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

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

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

If we continue to progress the development of our product candidates, results of preclinical studies, clinical trials or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results.
The results of preclinical studies, clinical trials or analyses of the results from such trials, may not be predictive of the results of later clinical trials. Product candidates in later clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and prior clinical trials or having shown promising results based on analyses of data from earlier trials. Late-stage clinical trials may include a larger number of patients and could differ in other significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, patient population, efficacy endpoints, dosing regimen and statistical design. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and post hoc analysis of results may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. We have completed Phase 1 clinical studies for RLYB116, however, even if we complete later clinical trials as planned, we cannot be certain that their results

will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

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

Enrollment and retention of patients in rare disease clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
If we continue to progress the development of our product candidates, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We currently are conducting clinical trials with our product candidates in rare disease indications, which can make completion of such trial more difficult. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the speed at which we can recruit eligible patients to participate in testing our product candidates and our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Clinical trial recruitment delays often result in increased costs, delays in advancing product development, delays in testing the effectiveness of technologies, delays in obtaining marketing approval or termination of clinical trials.

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

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

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

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

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

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

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

Adverse events or undesirable side effects caused by any product candidates we develop could cause us or regulatory authorities or IRBs, IECs or DSMBs, where applicable, to interrupt, delay, or halt clinical trials and, if we seek approval of any such product candidate, could result in a more restrictive label, imposition of a 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 of RLYB116. Patients may develop an allergic reaction to the drug and/or develop antibodies directed at RLYB116, or may require immunization with a meningococcal vaccine and prophylactic antibiotics. An immune response that causes adverse reactions or impairs the activity of RLYB116 could cause a delay in or termination of our development plans.

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

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

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label, limit the approved use of such product candidate, or otherwise restrict distribution or marketing such as through requiring adoption of a REMS program;
- we may be required to conduct additional clinical trials;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

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

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities that our product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing an active ingredient in our product candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, EMA or other comparable foreign regulatory authorities for approval;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States or the applicable foreign jurisdiction;
- we may be unable to demonstrate that our product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or NDA or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of our product candidates;
- additional time may be required to obtain regulatory approval for our product candidates because they are combination products;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the policies, regulations, and guidelines of the FDA, EMA or other comparable foreign regulatory authorities regarding the development, approval, and marketing of drugs and biologics may significantly change, including but not limited to, in the U.S., as a result of the 2025 change in presidential administration, which may render our clinical data insufficient for approval or restrict us from marketing our product candidates in the manner in which we anticipate.

We have never obtained marketing approval for a product candidate. If we continue to progress the development of our product candidates, any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability.

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

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

Our product candidates target rare diseases and conditions. With respect to RLYB116, we estimate that there are approximately 8,000 patients with immune PTR and up to 10,000 patients with refractory APS in the United States. Our projections of the number of eligible patients are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, population statistics and market research, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of eligible patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to. For example, even if we obtain FDA approval for RLYB116, the drug may be approved for a target population that is more limited than what we currently anticipate. Furthermore, even if we obtain significant market share for any product candidate, if approved, the potential target populations for our product candidates are for rare diseases, and we may never achieve profitability.

Further, in many cases there are either limited screening or diagnostic tests for the indications our product candidates are being developed to potentially treat. The lack of screening and diagnostic tests, coupled with the fact that there is frequently limited awareness among certain health care providers concerning the rare diseases we may seek to treat, often means that a proper diagnosis can, and frequently does, take years to identify (or an appropriate diagnosis may never be made for certain patients). As a result, even if one of our product candidates is approved for commercial sale, we may not be able to grow our revenues due to difficulty in identifying eligible patients. There can be no guarantee that any of our programs will be effective at identifying patients that will benefit from our product candidates, and even if we can identify patients that our product candidates can help, the number of patients that our product candidates may ultimately treat may turn out to be lower than we expect, they may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify, all of which may adversely affect our ability to grow and generate revenue and adversely affect our results of operations and our business. In addition, even in instances where we are able to expand the number of patients being treated, the number may be offset by the number of patients that discontinue use of the applicable product in a given period resulting in a net loss of patients and potentially decreased revenue.

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a product candidate we develop is approved, we will face intense competition. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development of products that may be like our product candidates or address similar markets. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. If we successfully develop and, if approved, commercialize RLYB116, this therapy may compete with anticoagulants such as Warfarin, or potentially be used in conjunction, with currently marketed treatments and any new therapies that may become available in the future.

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 43 days beginning on October 1, 2025 and for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. The Trump Administration has reduced the number of employees serving in government agencies, including the FDA. If a prolonged government shutdown occurs, or if the U.S. government takes other personnel actions, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and

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

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with the FDA's current 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 ("FDCA") and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

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

- restrictions on manufacturing such products;
- restrictions in the labeling or on the marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or additional post-marketing clinical trials;
- issuance of warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit, or delays in such approvals;
- recalls or market withdrawals of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or termination of ongoing clinical trials;
- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our products;
- product seizure; and
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

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

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

If we continue to progress the development of our product candidates, we may seek Fast Track designation, Breakthrough Therapy designation, or 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 RLYB116. The FDA has broad discretion whether to grant this designation, and we may not receive it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval and we may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a Breakthrough Therapy, the FDA may

later decide that such product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

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

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

If a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the same orphan designation for that time period, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the United States, the exclusivity period is seven years. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years in Europe if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA

later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Similarly, in the EU, the market exclusivity can be broken if the holder of the MA for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product. In addition, in both the United States and EU, if a different drug is subsequently approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity, which only protects against approval of the "same" drug for the same indication.

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

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

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

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

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

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

entering the market successfully. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product.

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

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

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

If we continue to progress the development of our product candidates, even if a product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Various factors will influence whether our product candidates are accepted in the market if approved for commercial sale, including, but not limited to:

- the efficacy, safety and tolerability of our products, and potential advantages compared to alternative treatments;
- the clinical indications for which the product is approved, and product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the effectiveness of sales and marketing efforts;
- the prevalence and severity of any side effects;

- the cost of treatment in relation to alternative treatments, including any similar treatments;
- our ability to offer our products for sale at competitive prices;
- the availability and access to screening and/or diagnostic tests;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and reimbursement for any of our products that are approved and any screening and/or diagnostic testing, as appropriate; and
- any restrictions on the use of our product together with other medications.

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

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

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the Affordable Care Act ("ACA") to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product, sponsor's data or submit the application as a biosimilar application. Any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

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

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

In order to market and successfully commercialize any product candidates we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in

marketing products. If we commercialize any of our product candidates that may be approved ourselves, we will need to develop an in-house marketing organization and sales force across rare disease therapeutic areas, which will require significant expenditures, management resources, and time. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retrain marketing and sales personnel. Any failure or delay in the development of a product candidate that affects the expected timing of commercialization of the product candidate or results in the failure of the product candidate to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses. Our investment would be lost if we are unable to retain or reposition our sales and marketing personnel.

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

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

Risks Related to Our Dependence on Third Parties

If we continue to progress the development of our product candidates, we may pursue business development transactions and collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing or out-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources.
We acquired all rights to RLYB116 and RLYB114 from Sobi in 2019. We also obtained worldwide exclusive rights to RLYB332 from Sanofi in 2022. If we continue to progress the development of our product candidates, we may acquire or in-license rights to product candidates, products or technologies, acquire other businesses or enter into collaborations with third parties. We may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions, in-licenses or collaborations may not strengthen our competitive position, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to incur debt in connection with an acquisition, or in-license or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of our existing stockholders.

We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

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

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

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborations on acceptable terms or to successfully transition away from terminated collaborations, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense, or find alternative sources of capital, which would have a material adverse impact on our clinical development plans and business. If we fail to establish and maintain collaborations related to our product candidates, we could bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional

employees and otherwise develop expertise for which we have not budgeted. This could negatively affect the development and commercialization of our product candidates.

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

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

As of May 8, 2026, we had 9 full-time employees, upon whom we rely for various administrative, research and development, business development and other support services shared among our subsidiaries. The size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries, including their research and development activities, the management of financial, accounting, and reporting matters, and the oversight of our third-party vendors and partners. If our centralized team or our third-party vendors and partners performing such functions fail to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

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

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

We currently rely and will rely on third parties for the manufacture of drug substance and drug product for our preclinical studies and clinical trials and, if we continue to progress the development of our

product candidates, expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. Our reliance on third parties may increase the risk that we will not have sufficient quantities of such drug substance, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing RLYB116 or any other product candidate. Instead, we rely on and expect to continue to rely on contract manufacturers for the supply of cGMP-drug substance and drug product of RLYB116 and any other product candidates we develop and, in the future, for commercial supply. Reliance on third parties may expose us to more risk than if we were to manufacture our product candidates ourselves.

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

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

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

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

The facilities and processes used to manufacture our product candidates are subject to inspection by the FDA, EMA and other comparable foreign authorities. If the FDA, EMA or other comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities or conduct additional studies, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work.

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

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

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

Our collaborators also may breach their agreements with us or otherwise fail to perform to our satisfaction, which could impact the development timeline of our product candidates.

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

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

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

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

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

Risks Related to Healthcare Laws and Other Legal Compliance Matters

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

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes, and additional proposed changes, to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of health care. As an earlier example with longstanding impact, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. The ACA expanded health care coverage through a Medicaid eligibility expansion and the implementation of the individual mandate for health insurance coverage. The ACA also imposed an annual fee payable on manufacturers of branded prescription drugs and biologic agents (other than those designated as orphan drugs) and implemented changes to the coverage and reimbursement of drug products under government healthcare programs, including an expansion in the Medicaid drug rebate program, an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid drug rebate program, and the establishment of a new Medicare Part D coverage gap discount program.

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

Recently, drug pricing and payment has been subject to a number of reform initiatives. For example, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-

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

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

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

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

Other recent government actions may also affect prices or payments for prescription drugs. For example, the Trump Administration's recently announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

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

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

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

- U.S. federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;

- U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- U.S. 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 calculate, report and certify certain complex product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- U.S. federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to CMS for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or report information related to payments to health care providers, marketing expenditures or drug prices; state and local laws requiring the registration of pharmaceutical sales representatives; state laws regulating the manufacture and distribution of biopharmaceutical products; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- U.S. laws and regulations prohibiting bribery and corruption, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended ("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 EU/European Economic Area ("EEA") (including health data). See "—Our business operations may subject us to data protection laws, including the GDPR, the United Kingdom ("UK") GDPR, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, "CCPA") and other similar laws."

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

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

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

The GDPR and UK GDPR apply to companies established in the EEA and UK, respectively, as well as to companies that are not established in the EEA or UK, respectively, and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA or UK, respectively. If we conduct clinical trial programs in the EEA or UK (whether the trials are conducted directly by us or through a clinical vendor or collaborator), enter into research collaborations involving the monitoring of individuals in the EEA or UK, or market our products to individuals in the EEA or UK, we will be subject to the GDPR or UK GDPR, as applicable, which place stringent operational requirements for processors and controllers of personal data of individuals in the EEA and UK, respectively. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR or UK GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, temporary or definitive bans on data processing, or fines of up to 20 million Euros in the case of GDPR or £17.5 million in the case of UK GDPR or, in each case, up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

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

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

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

In the United States, the CCPA imposes many obligations for the collection, processing, and sharing of personal information of California residents. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Because we have not yet generated revenue and do not meet the CCPA's other jurisdictional tests, we do not yet meet the applicable threshold for the CCPA to apply to our business. If our business becomes subject to CCPA in the future, it could increase our compliance costs and potential liability. Similar laws have been proposed or passed in more than half of the states in the U.S. and in the U.S. Congress. In addition, Washington state enacted the My Health, My Data Act, a health-focused consumer privacy law, which took effect in March 2024. This law imposes obligations related to the collection and sharing of certain health-related information that is not subject to HIPAA and that does not fall within certain other exceptions in the law. Other states have enacted, or are in the process of enacting, similar health-focused consumer privacy laws. Furthermore, all fifty U.S. states, the District of Columbia, Puerto Rico, and other U.S. territories have enacted data breach notification laws that require, among other things, notifications to state governments and/or the affected individuals in the event of a data breach. Such laws differ from one another, and may impose significant compliance burden. Further, we may at times fail, or be perceived to have failed, to have complied with such laws. This could result in significant consequences, which include, but are not limited to, the imposition of fines and penalties, government enforcement actions, investigations and other proceedings, as well as additional reporting requirements and/or oversight.

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

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

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

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize similar or identical technology and products, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
Our success depends in large part on our ability to obtain and maintain intellectual property, particularly patents, in the United States and other countries, with respect to any proprietary technology and product candidates we develop. If we are unable to obtain or maintain patent protection of proprietary technology or product candidates by filing patent applications and/or in-licensing related intellectual property in commercially relevant jurisdictions, our business, financial condition, results of operations and prospects could be materially harmed.

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

The patent rights of pharmaceutical and biotechnology companies generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged in the United States or in numerous foreign jurisdictions. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter.

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

value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or, in some cases, are not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are uncertain. In addition, the scope of patent protection outside the United States is uncertain, and laws of foreign countries might not protect our rights to the same extent as the laws of the United States or vice versa.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they might not issue in a form that will provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents might be challenged in a variety of proceedings before courts or patent offices in the United States and abroad. Such challenges might result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology without payment to us, and/or limit the duration of the patent protection of our technology and product candidates. If the breadth or strength of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Obtaining and maintaining patent protection depends on compliance with various procedural requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
The U.S. Patent and Trademark Office ("USPTO") and foreign patent offices have a number of procedural and documentary requirements that must be complied with during the patent application and prosecution process. Periodic fees must be paid to the USPTO and foreign patent offices at several stages or annually over the lifetime of issued patents and pending patent applications. In certain circumstances, we might rely on our licensing partners to meet procedural, documentary, and fee requirements of the relevant patent agency. With respect to our patents, we rely outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors fail to maintain current and future patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.
Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, third parties may attempt to develop and/or commercialize competitive products in foreign countries where we do not have any patent protection and/or where legal recourse may be limited. Further, we may not be able to prevent third parties from importing products made using our inventions into the United States or other jurisdictions. This may have a significant commercial impact on our business operations.

Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and even if we do

prevail, the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

In addition to legislative changes, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Further, political changes in government leadership both within and outside of the U.S. could result in changes to national patent laws and regulations or multi-country intellectual property treaties, which could impact patent enforcement in the U.S. and internationally. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

In addition to our existing licensing agreements, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, if approved, in which case we would be required to obtain a license from these third parties. The in-licensing and acquisition of third-party intellectual property rights

is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. These factors might mean fewer suitable licensing opportunities for us, as well as higher acquisition or licensing costs.

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

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

If we fail to comply with our obligations in our intellectual property licenses with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business. We are party to license agreements that impose upon us certain obligations, and we may enter into additional licensing and funding arrangements with third parties that may impose, among other things, diligence, development, and commercialization timelines, milestone and royalty payments, and insurance If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might be forced to cease developing, manufacturing or marketing any product that is covered by these agreements or may face other penalties under such agreements, or our counterparties may require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement.

Termination or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements may result in our loss of rights or our having to negotiate new or reinstated agreements with less favorable terms, which would impede, delay or prohibit the further development or commercialization of any product candidates that rely on such agreements.

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

- the scope of rights granted under the license agreement and other matters of contract interpretation;
- whether and the extent to which our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- the sublicensing of patent and other rights under collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

The resolution of any contract disagreement that may arise could narrow the scope of our rights to the relevant intellectual property or technology, could increase our financial or other obligations under the relevant agreement, or could result in loss of some or all rights under the license agreement. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates. Any of these outcomes could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patent terms may not protect our competitive position for an adequate amount of time.
Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours during periods when commercial exclusivity would be valuable to us.

If we do not obtain a patent term extension for any product candidates we might develop, our business might be materially harmed.
In the United States, the term of a patent that covers an FDA-approved drug may be eligible for a patent term extension ("PTE") of up to five years beyond the expiration date of the patent, as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a PTE of up to five years beyond the expiration date of the patent. The length of the PTE is related to the length of time the drug is under regulatory review, and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. The patent term of only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other jurisdictions. While we expect to apply for PTE on patents covering our product candidates, there is no guarantee that such extensions will be granted and, even if granted, the length of such extensions. We may not be granted PTE either in the United States or in any foreign country, even where that patent is eligible for PTE, if, for example, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Furthermore, for licensed patents, we might not be able to control whether a petition to obtain a PTE is filed or obtained from the USPTO and/or foreign patent office(s). If we are unable to obtain any PTE, or if the term of extension is less than we request, our business, financial condition, results of operations and prospects could be materially harmed.

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

In addition to seeking patents for some of our technology and product candidates, we seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we cannot guarantee that we have entered into confidentiality agreements with each party that may have or has had access to our trade secrets or proprietary technology.

Over time, our trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

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

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.
We might be unable to successfully register our trademarks and trade names, and/or to establish name recognition based on our trademarks and trade names, which could result in substantial costs and diversion of resources, and could adversely impact our ability to compete effectively. In addition, our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using them. At times, competitors may adopt trademarks or trade names similar to ours, impeding our ability to build brand identity, and possibly leading to market confusion. In addition, we could be subject to trademark or trade name infringement claims brought by owners of other registered trademarks or trade names

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

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

An adverse result in any such proceeding could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not yielding an issued patent. A court may also refuse to enjoin a third-party from using the technology at issue, for example, on the basis that patents do not cover that

technology. Furthermore, if the breadth or strength of protection provided by our current or future patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or services. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our research programs and clinical trials.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO might be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of interference or derivation proceedings might fail and, even if successful, might result in substantial costs.

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

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

Third parties may allege that we are violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.
Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are pursuing development candidates. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property rights.

Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Adversarial proceedings might also be initiated by patent holding companies or other adverse patent owners who have no relevant product or service revenue, and against whom our own patents might provide little or no deterrence or protection. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain greater visibility as a public company.

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

Parties making claims against us may obtain injunctive or other equitable relief that could block our ability to commercialize our product candidates. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, collaborators or other third parties; seek new regulatory approvals; and/or redesign our infringing products, which may not be possible or practical. In addition, if we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we may be required to obtain a license to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. Further, a license could require us to make substantial licensing and royalty payments.

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

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

If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cost substantial resources.
Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements involving such proceedings, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient resources to conduct such litigation or proceedings adequately. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

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

- we or our license partners or current or future collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending or future patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to seek patent protection in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

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

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

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

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

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

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

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

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

Our proprietary or confidential information may be lost, or we may suffer security breaches.
The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions.

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

Risks Related to Our Common Stock

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

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

The market price of our common stock may be volatile, which could result in substantial losses for investors.
Shares of our common stock were offered in our IPO in July 2021 at a price of $104.00 per share and between the date of our IPO and May 8, 2026, the closing price per share of our common stock has ranged from as low as $2.00 to as high as $187.20. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- effects of public health crises, pandemics and epidemics;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section and elsewhere in this 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 May 8, 2026, we have 5,298,137 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 May 8, 2026, we also have pre-funded warrants to purchase up to an aggregate of 416,673 shares of common stock outstanding. We may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder's election upon 61 days' notice to us subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99%.

Moreover, as of March 31, 2026, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On May 9, 2023, we registered an aggregate of 1,543,950 shares of common stock held by holders with registration rights, for resale, pursuant to a registration statement on Form S-3. In addition, we have entered into the Sales Agreement with TD Cowen to offer and sell shares of our common stock having an aggregate offering price of up to $100,000,000, from time to time, through an at-the-market offering program. We also registered an aggregate of 1,737,094 shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

Our directors and executive officers and their affiliates beneficially own shares representing approximately 25% of our outstanding common stock as of May 8, 2026. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We could be subject to securities class action litigation.

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

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

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.
We are an "emerging growth company," as defined in the JOBS Act and we may remain an EGC until December 31, 2026. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX Section 404"), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

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

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.
Our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;

- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

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

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

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

Our amended and restated certificate of incorporation designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts (as appropriate) within the State of Delaware are exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) action against us or any of our directors or officers involving a claim or defense arising pursuant to the Exchange Act or the Securities Act, or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This exclusive forum provision does not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision does not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our

business and financial condition. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are “facially valid” under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid.

General Risks

A variety of risks associated with operating internationally could materially adversely affect our business.
Our business strategy includes potentially expanding internationally. Doing business internationally involves several risks, including, but not limited to:

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

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

U.S. federal income tax reform could adversely affect our business and financial condition.
The rules dealing with U.S. federal, state, and local income taxation are constantly under review through the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act, (the "TCJA"), was enacted in 2017 and significantly reformed the Code. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic,

including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. There also may be technical corrections legislation or other legislative changes proposed with respect to the TCJA and CARES Act, the effects of which cannot be predicted and may be adverse to us or our stockholders. Additionally, the IRA was enacted in August 2022.

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

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

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

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including changes in tariffs and other trade restrictions. A severe or prolonged economic downturn, period of sustained increased inflation, tariffs and other trade restrictions or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Further, geopolitical instability outside the United States may also impact our operations or affect global markets, such as the invasion of Ukraine by Russia and the Israel-Hamas war. While we do not currently conduct clinical trials in Ukraine, Russia, or the Middle East, we cannot be certain what the overall impact of these events will be on our business or on the business of any of our third-party partners, including our contract research organizations, contract manufacturers or other partners. The impact of these events could also expand into other markets where we do business. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which current geopolitical tensions, the economic climate and the financial market conditions could adversely impact our business.

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

As a public company, we have incurred, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Item 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 March 31, 2026.

Item 5. Other Information

Director and Officer Trading Arrangements

During the quarter ended March 31, 2026, 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
2.1	Agreement and Plan of Merger and Reorganization among Rallybio Corporation, Farmington Merger Sub, Inc. and Candid Therapeutics, Inc., dated as of March 1, 2026 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on March 2, 2026)
2.2	Waiver, dated as of May 1, 2026, by and among Rallybio Corporation, Candid Therapeutics, Inc. and UCB S.A.
10.1*†	Separation Agreement, dated March 31, 2026, by and between Rallybio Corporation and Steven Ryder, MD.
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.

† Indicates management contract or compensatory plan

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: May 13, 2026

By: /s/ Stephen Uden

Stephen Uden, M.D.

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

Date: May 13, 2026

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber

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

CONFIDENTIAL RELEASE AND SEPARATION AGREEMENT

This Confidential Release and Separation Agreement ("**Agreement**") is made by and between Steven Ryder, M.D. ("**Employee**" or "**you**"), on behalf of yourself and your agents, assignees, heirs, executors, administrators, beneficiaries, trustees, legal representatives and assigns (collectively "**Employee Parties**"), and Rallybio Corporation, its subsidiaries, parents, affiliates, divisions and related entities (the "**Company**"), on behalf of its and their successors, predecessors, assigns, present or former directors, officers, executives, agents, attorneys, shareholders, fiduciaries or employees or any person acting on behalf of any of them (collectively, the "**Company Released Parties**").

WHEREAS, you were employed by the Company; and

WHEREAS, the Company conducted a reduction in force in connection with entering into the Merger Agreement (as defined below), which reduction resulted in the termination of your employment with the Company; and

WHEREAS, you and the Company wish to enter into this Agreement to fully resolve any actual or potential claims, including without limitation claims arising out of your employment with and/or separation from the Company;

NOW, THEREFORE, in consideration of the promises and mutual covenants set forth herein, **Employee** and the **Company** agree as follows:

1. End of Employment. Your employment with the Company ended effective [ ] (the "**Separation Date**"). Regardless of whether you sign this Agreement, you will be paid your base salary through the Separation Date. You acknowledge that (a) with the receipt of your final paycheck, you will have received all compensation and benefits that were due to you through the Separation Date as a result of services performed for the Company, except as provided in this Agreement; and (b) you have reported to the Company any and all work-related injuries incurred during your employment.

2. Status of Employee Benefits; Equity Awards; Exercisability of Stock Options.

(a) Except for any right you may have to continue your participation and that of your eligible dependents in the Company's medical, dental, and vision plans under the federal law known as "COBRA" or similar applicable law (together, "**COBRA**"), and except as provided for in Section 3(b) or Section 3(d) of this Agreement, your participation in all employee benefit plans of the Company ended as of the Separation Date, in accordance with the terms of those plans. You acknowledge that you have not continued to earn paid time off or other similar benefits after the Separation Date. You will receive information about your COBRA continuation rights under separate cover.

(b) Your rights and obligations with respect to any restricted stock, stock options and other equity or equity-based awards granted to you by the Company which were outstanding as of the Separation Date shall be governed by the applicable equity incentive plan and the award agreement evidencing such award, subject to Section 3(d) below.

3. Consideration. In exchange for your execution of and compliance with this Agreement, and provided that you do not revoke this Agreement as set forth in Section 19, the Company will provide you with the benefits set forth below in this Section 3.

(a) ***Severance Pay*.** The Company will pay you severance pay in an amount equal to twelve (12) months of your base salary as of your Separation Date, which amount will be paid to you in installments on the Company's regular payroll dates beginning with the first practicable payroll date following the Effective Date (defined in Section 19).

(b) ***COBRA.*** Provided that you make an effective and timely election to continue your participation in the Company's group health insurance plans pursuant to COBRA, the Company will contribute to the premium costs of your monthly COBRA continuation coverage, including your portion of the COBRA premium costs, at the same rate that it contributes from time to time to group medical, dental and/or vision insurance premiums (as applicable) for its active employees until the earliest of (i) twelve (12) months following the Separation Date, (ii) the date that you and your eligible dependents cease to be eligible for such COBRA coverage and (iii) the date on which you obtain health coverage from another employer, payable beginning with the first payroll date following the Effective Date (defined in Section 19).

(c) ***Outplacement Services***. You will be provided outplacement services through an outplacement service provider selected by the Company. You will not be entitled to the cost of outplacement services if you choose not to elect them or if you do not elect the outplacement services in a timely manner.

(d) ***Change in Control***. Upon the consummation of the transactions contemplated by the certain Agreement and Plan of Merger (the "**Merger Agreement**"), dated as of March 1, 2026, by and among the Company, Farmington Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company, and Candid Therapeutics, Inc., a Delaware corporation, in lieu of the amounts set forth in subsections (a) and (b) above, you shall be entitled to the amounts set forth in subsections (i) and (ii) below (it being understood that any amounts paid under subsections (a) and (b) above shall count against the amounts payable under subsections (i) and (ii) below so that there is no double counting of the same monthly amount):

(i) ***Severance Pay*.** The Company will pay you severance pay in an amount equal to one and one half (1.5) times the sum of your base salary and your target annual base salary as of the Separation Date, which amount will be paid to you in installments on the Company's regular payroll dates.

(ii) ***COBRA.*** Provided that you make an effective and timely election to continue your participation in the Company's group health insurance plans pursuant to COBRA, the Company will contribute to the premium costs of your monthly COBRA continuation coverage, including your portion of the COBRA premium costs, at the same rate that it contributes from time to time to group medical, dental and/or vision insurance premiums (as applicable) for its active employees until the earliest of (i) eighteen (18) months following the Separation Date, (ii) the date that you and your eligible dependents cease to be eligible for such COBRA coverage and (iii) the date on which you obtain health coverage from another employer.

(iii) ***Equity Awards***. Any restricted stock, stock options and other equity or equity-based awards granted to you by the Company which were outstanding as of the Separation Date shall remain outstanding and eligible to vest in accordance with the terms of the Merger Agreement, with any stock options granted to you that were vested and unexercised as of the Separation Date and any stock options that become vested under the terms of the Merger Agreement remaining exercisable until ninety (90) days following the closing of the transactions contemplated by the Merger Agreement; (or, if earlier, until the original expiration date of such stock option). You acknowledge and agree that, by reason of the extension of the post-termination exercise period described in the foregoing sentence, any stock option held by you that is intended to qualify as an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**") will be treated as a non-qualified stock option. Nothing herein, however, constitutes tax advice to you and you are urged to consult your own independent tax advisors regarding the tax treatment of any equity awards that you hold.

(d) ***Withholding Taxes***. All payments made by the Company under this Agreement shall be reduced by any tax or other amounts required to be withheld by the Company under applicable law and all other lawful deductions authorized by you.

4. Non-Admission. The Company's offer of this Agreement to you and any payments made under this Agreement do not constitute an admission by the Company that you have any claim of any kind against the Company or that the Company admits to any liability.

5. Release.

(a) In exchange for the consideration described in Section 3 of this Agreement, and provided that you do not revoke this Agreement as set forth in Section 19, you and the Employee Parties agree to release the Company and the Company Released Parties from all known and unknown claims of any type through the date you execute this Agreement, including without limitation, any known or unknown claims arising out of anything having to do with your employment with the Company or the end of your employment. This means that you and the Employee Parties give up these claims to the fullest extent permitted by law, including without limitation:

i. claims for any pay, compensation or benefits, bonuses, commissions, incentive pay, paid or unpaid leave or time off, salary, separation or severance pay or benefits, wages, unpaid accrued vacation or other paid time off, overtime, unvested equity, or any other form of compensation whatsoever (including penalties for non-payment), costs, damages, interest, expenses or insurance;
ii. claims concerning any express or implied employment contracts, covenants or duties;
iii. claims for defamation; detrimental reliance; fraud; impairment/loss of business/economic opportunity; insufficiency of termination notice; intentional/negligent infliction of emotional distress; interference with contractual or legal rights; invasion of privacy; loss of consortium; misrepresentation; negligence including negligent hiring/retention/supervision; personal injury; premises liability; promissory estoppel; public policy violation; retaliatory discharge; tortious interference; posting

requirement violations; records access violations; wrongful termination; or any other federal, state, local or common law claims;

iv. claims of discrimination based on age, ancestry, benefit entitlement, color, concerted activity, disability, failure to accommodate, gender, gender identity or expression, genetics, harassment, income source, leave rights, marital status, military status, national origin, parental status, perception of a protected characteristic, political affiliation, race, religion, retaliation, sex, sexual orientation, union activity, veteran status or other legally protected status; claims that any payment under this Agreement was affected by any such discrimination; or any other claims under Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1866; the Civil Rights Act of 1991; the Equal Pay Act of 1963; the Age Discrimination in Employment Act ("ADEA") and the Older Workers Benefit Protection Act; the Americans with Disabilities Act; the Family and Medical Leave Act; the Employee Retirement Income Security Act; the Sarbanes-Oxley Act of 2002; or the False Claims Act; each as amended;

v. claims arising under state or local law, including, but not limited to, the Connecticut Fair Employment Practices Act, Conn. Gen. Stat. §§ 46a-51 *et seq.*; the Connecticut Human Rights and Opportunities Act, Conn. Gen. Stat. § 46a-60; the Connecticut Equal Pay Law, Conn. Gen. Stat. § 31-75; and the Connecticut Family and Medical Leave Law, Conn. Gen. Stat. §§ 31-51kk *et seq*, each as amended; and

vi. any right to be or remain a member of any class or collective action against the Company or the Company Released Parties.

You acknowledge and agree that, as a condition of this Agreement, you and the Employee Parties expressly release all rights and claims against the Company or the Company Released Parties that you know about, as well as those you may not know about. For the purpose of implementing a full and complete release and discharge of the Company, the Company Released Parties, and others released herein, you expressly acknowledge that this Agreement is intended to include and does include in its effect, without limitation, all claims which you do not know or suspect to exist, and that this Agreement contemplates the extinguishment of any such claim or claims, except to the extent precluded by federal, state or local statutes.

(b) Notwithstanding any other provision of this Agreement, nothing contained herein is intended to prohibit or restrict Employee in any way from: (i) making any disclosure of information required by law or requested by any regulatory agency; (ii) exercising Employee's rights under the OWBPA to challenge the validity of Employee's waiver of claims arising under the ADEA as set forth in subparagraph (a), above; (iii) pursuing claims which by law cannot be waived or subject to a general release of this kind, such as claims for unemployment or workers' compensation benefits; (iv) bringing appropriate proceedings to enforce this Agreement; (v) exercising Employee's rights to indemnification under any agreement with the Company or its affiliates or under the Company's organizational documents or exercising Employee's rights under any directors and officers insurance or similar policy; or (vi) providing information to, filing a charge with, or testifying or otherwise assisting in any investigation or proceeding brought by, any federal or state agency, including, without limitation, the Equal Employment Opportunity Commission ("EEOC") or any state equivalent agency; the Securities and Exchange Commission; the Department of Justice; the Congress; any agency Inspector General; or the Company's legal, compliance or human resources officers. However, to the fullest extent permitted by applicable law, Employee hereby waives any

right to recover any monetary damages in connection with a charge or proceeding brought by Employee or through any action brought by a third party with the EEOC or any state equivalent agency with respect to the claims released and waived in this Agreement, other than with respect to any "whistleblower"-type claim. Employee acknowledges that as of the date Employee signs this Agreement, Employee has not filed or caused to be filed any lawsuits, claims, complaints, actions, proceedings or arbitrations in any form or forum against the Company or any of the Company Released Parties.

(c) In accordance with the requirements of the OWBPA, the Company has also provided you, as Appendix A to this Agreement, a list of the job titles and ages or all employees in your decisional unit (as described therein) who have been selected for layoff and are eligible for severance benefits at this time, together with the job classifications and ages of all individuals in your decisional unit who have not been selected for layoff and therefore are not eligible for severance benefits at this time.

6. Disclosure. In addition to the foregoing, and in further exchange for the consideration described in Section 3 of this Agreement, you specifically represent and warrant that as of the date that you execute this Agreement, either you (i) have disclosed to the Company's General Counsel or to another member of the Company's internal Legal Department in writing any matter that you know, suspect or have reason to know or suspect could constitute an actual or potential violation of the Company's Code of Business Conduct and Ethics, or similar code of business conduct and ethics, or of any internal or external legal, regulatory or compliance requirement applicable to the Company in any jurisdiction in which it does business, or (ii) have no information concerning any such matter.

7. Promise Not to Sue. Without limiting your rights under Section 13 of this Agreement, you promise not to sue the Company or any Company Released Party for any claims covered by Section 5 of this Agreement, and not excluded by any other section of this Agreement. This promise not to sue is separate from and in addition to your promises in Section 5 of this Agreement.

8. Confidential Terms. You agree that, except as required by applicable federal, state, or local law, you will keep all of the terms of this Agreement strictly confidential, including the amount of the payment provided to you under this Agreement and the fact of this Agreement ("**Confidential Terms**"). Subject to the second and third sentences of Section 13 of this Agreement, you will not disclose these Confidential Terms to anyone except your immediate family members and your legal/financial advisors, except to the extent required to comply with or enforce this Agreement, or as required to comply with: a subpoena, a court order, the submission of information to tax or unemployment authorities, or another similar legal process. If you disclose Confidential Terms to immediate family members or legal/financial advisors, then each such person is bound by this provision, and a disclosure by any of them will be considered a disclosure by you. You further represent that prior to executing this Agreement, you have not disclosed its terms in a manner inconsistent with this confidentiality provision. Nothing in this Agreement will be construed to prohibit Employee from engaging in protected concerted activity under the NLRA, if applicable.

9. Nondisparagement. Subject to Employee's rights pursuant to Section 5(b) and the second and third sentences of Section 13 of this Agreement, you agree not to make comments

injurious to the reputation of the Company or the Company Released Parties or otherwise disparage the Company or the Company Released Parties. Any disclosure by you in good faith in connection with any legal proceedings between you and the Company, in response to legal process, required governmental testimony or filings, or administrative or arbitral proceedings (including, without limitation, depositions in connection with such proceedings) shall not be deemed to violate this Section 9.

10. Continuing Obligations. You acknowledge and agree that the restrictive covenants in the Confidential Information, Non-Competition and Invention Assignment Agreement which you signed in connection with your employment (collectively, the "**Continuing Obligations**"), survive your separation from the Company and remain in full force and effect, subject to the second and third sentences of Section 13 of this Agreement. Without limiting your obligations under the Continuing Obligations, you agree to comply with the covenants listed below following the Separation Date.

11. Return of Company Property. You agree that you have returned or will return immediately, all property belonging to the Company, including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or any property belonging to the Company and any Company documents. You also agree to disclose to the Company all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, any information which you have password-protected on any computer equipment, network or system of the Company. By your signature below, you warrant and representation that you have conducted a thorough search for Company property in all such electronic document storage accounts and electronic devices, as well as all files and hard copy documents in your possession, custody, or control.

12. Cooperation. You agree to cooperate with, and assist, the Company to ensure a smooth transition of your work responsibilities. At any time following the Separation Date, you will provide such information as the Company may reasonably request with respect to any Company-related transaction or other matter in which you were involved in any way while employed by the Company. You further agree to assist and cooperate with the Company in connection with the defense, prosecution, government investigation, or internal investigation of any claim or matter that may be made against, concerning, or by the Company. Such assistance and cooperation shall include timely, comprehensive, and truthful disclosure of all relevant facts known to you, including through in-person interview(s) with the Company's internal Legal Department or outside counsel for the Company. You shall be entitled to reimbursement for all properly documented expenses incurred in connection with rendering services under this Section, including, but not limited to, reimbursement for all reasonable travel, lodging, and meal expenses.

13. Non-Interference with Rights. The Release set forth in Section 5 of this Agreement excludes any claims for breach of this Agreement, claims challenging the enforceability of this Agreement under the ADEA, and claims which cannot be waived by law, such as claims for unemployment or worker's compensation benefits, or claims for vested/earned benefits under ERISA-covered employee benefit plans. **Further, you understand, agree and acknowledge that nothing contained in this Agreement, including but not limited to Sections 5 (Release), 6 (Disclosure), 7 (Promise Not to Sue), 8 (Confidential Terms), 9 (Nondisparagement), 10 (Continuing Obligations), 11 (Return of Company Property), 12 (Cooperation), will prevent,**

prohibit or restrict you from reporting possible violations of any law or regulation to, making disclosures to, and/or participating or cooperating in any investigation or proceeding conducted by the National Labor Relations Board ("NLRB"), the EEOC, the U.S. Department of Labor, the Securities and Exchange Commission, and/or any other governmental agency or entity charged with the enforcement of any laws, or from exercising rights under Section 7 of the National Labor Relations Act to engage in joint activity with other employees, except that you acknowledge that, to the maximum extent permitted by law, you are waiving your right to recover any benefits, including without limitation monetary damages, in connection with any such claim, charge or proceeding brought against the Company, regardless of who filed or initiated any such complaint or charge and/or in what forum such complaint or charge is brought in. Notwithstanding any other provision in this Agreement, you are not required to seek authorization from the Company or to notify the Company before making any such report or disclosure, or before participating or cooperating in any investigation or proceeding. You acknowledge that you have been notified in accordance with the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1833(b), that you will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. You further acknowledge that you have been notified that if you file a lawsuit for retaliation against the Company for reporting a suspected violation of law, you may disclose the Company's trade secrets with your attorney and use the trade secret information related to that suspected violation of law in the court proceeding if you: (a) file any document containing the trade secret under seal; and (b) do not disclose the trade secret, except pursuant to court order. Notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means.

14. Remedies. You agree that if you are found to have violated this Agreement, you will pay the Company's reasonable attorneys' fees, court costs and other expenses to enforce this Agreement, in addition to any other available relief. Without limiting the foregoing, you further acknowledge and agree that, if you violate the terms of this Agreement by, without limitation, violating the covenants in Sections 5 (Release), 6 (Disclosure), 7 (Promise Not to Sue), 8 (Confidential Terms), 9 (Nondisparagement), 10 (Continuing Obligations), 11 (Return of Company Property), or 12 (Cooperation), the Company may (a) recapture the value of any proceeds from the exercise or sale of equity awards that were unvested as of the Separation Date, (b) require you to return all but $100.00 of the payments and benefits provided to you under this Agreement, and (c) suspend payment of any further payments and benefits provided to you under this Agreement. Nothing herein shall limit your rights under Section 13 of this Agreement.

15. Choice of Law and Forum. This Agreement shall be governed by and construed under the laws of the State of Connecticut, without regard to its conflicts of law rules. You and the Company hereby consent to the jurisdiction of the federal and state courts located in the State of Connecticut to resolve any disputes arising out of the interpretation or administration of this Agreement.

16. Successors. This Agreement shall be binding upon and inure to the benefit of you and the Employee Parties, the Company, the Company Released Parties, and their respective heirs,

representatives, executors, administrators, successors, insurers, and assigns, and shall inure to the benefit of each and all of them.

17. Severability. The provisions of this Agreement are severable, and if any part of it is found to be unenforceable or invalid, the other Sections shall remain fully valid and enforceable.

18. Representations. You acknowledge and agree that:

(a) you are advised, and by being given a copy of this Agreement and the enclosed Appendix A, have been advised to consult with an attorney of your own choice, and you have been given the opportunity to do so prior to signing this Agreement;

(b) you have not been promised anything besides what is in this Agreement;

(c) the payments and benefits described in this Agreement exceeds the amount that you otherwise would receive at the end of your employment with the Company and provides adequate and sufficient consideration to support this Agreement;

(d) you have reviewed this Agreement and are signing this Agreement knowingly and voluntarily;

(e) you have not been coerced or threatened into signing this Agreement;

(f) you do not have any pending court or administrative complaint or action against the Company;

(g) you were not required to waive any attorneys' fees as a condition of this Agreement; and

(h) this Agreement can only be modified in a written document signed by both you and the Company.

19. Time Periods. You are given forty-five (45) days from the date you receive this Agreement to consider it before executing it ("**Consideration Period**"). You may sign this agreement any time after your Separation Date and before the close of business on the final day of the Consideration Period. If you sign this Agreement prior to the end of the Consideration Period, your signature constitutes a voluntary waiver of this Consideration Period. You agree with the Company that changes to this Agreement, whether material or immaterial, do not restart the running of the Consideration Period.

You will have seven (7) calendar days after you sign this Agreement to revoke it ("**Revocation Period**") by providing written notice to the Company during the Revocation Period. Any revocation must be made in writing, postmarked no later than the close of business on the 7th day of the Revocation Period and addressed to:

Danielle Camputaro
Human Resources

Rallybio Corporation
234 Church Street, Suite 1020
New Haven, CT 06510

This Agreement will not become effective or enforceable until the Revocation Period has expired ("**Effective Date**"). If you do not revoke this Agreement, you will be entitled to the extension of the post-termination exercise period of any stock options held by you as set forth in Section 2(b) of this Agreement and receive the consideration described in Section 3 of this Agreement.

Notwithstanding anything to the contrary in this Agreement, if the Consideration Period or the Revocation Period spans two calendar years, any payments to which you become entitled under this Agreement following the Effective Date will be paid in the second calendar year to the extent such payments constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code ("**IRC §409A**").

20. Section 409A. This Agreement is intended to comply with the applicable requirements of IRC §409A and shall be construed accordingly. All references in this Agreement to termination of employment, a termination, retirement, cessation of employment, separation from service, and correlative terms, that result in the payment or vesting of any amounts or benefits that constitute "nonqualified deferred compensation" within the meaning of IRC §409A shall be construed to require a Separation from Service (as defined below), and the date of such termination in any such case shall be construed to mean the date of the Separation from Service. Each of the payments required to be made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments for purposes of IRC §409A. If you are a Specified Employee (as defined below) on the Separation Date, if any payment hereunder that is payable by reason of the termination of your employment constitutes "nonqualified deferred compensation" subject to IRC §409A and would otherwise have been required to be paid during the six (6)-month period following such termination of employment, it shall instead be delayed and paid, without interest, in a lump sum on the date that is six (6) months and one (1) day after your termination of employment (or, if earlier, the date of your death). You are solely responsible for any tax penalties that may be imposed on you as a result of IRC §409A. In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of IRC §409A. For purposes of the foregoing:

"**Separation from Service**" shall mean a "separation from service" (as that term is defined at Section 1.409A-1(h) of the Treasury Regulations under IRC §409A after giving effect to the presumptions contained therein) from the Company and from all other corporations and trades or businesses, if any, that would be treated as a single "service recipient" with the Company under Section 1.409A-1(h)(3) of such Treasury Regulations. The Board of Directors of Rallybio Corporation (the "**Board**") or the Compensation Committee thereof (the "**Committee**") may, but need not, elect in writing, subject to the applicable limitations under IRC §409A, any of the special elective rules prescribed in Section 1.409A-1(h) of the Treasury Regulations for purposes of determining whether a "separation from service" has occurred. Any such written election shall be deemed part of this Agreement; and

"**Specified Employee**" shall mean an individual determined by the Board, the Committee, or their delegate, to be a specified employee as defined in subsection (a)(2)(B)(i) of IRC §409A. The Committee may, but need not, elect in writing, subject to the applicable limitations under IRC §409A, any of the special elective rules prescribed in Section 1.409A-1(i) of the Treasury Regulations for purposes of determining "specified employee" status. Any such written election shall be deemed part of this Agreement.

21. Entire Agreement. This Agreement and its exhibits (if any) set forth the entire agreement between the parties. You are not relying on any other agreements or oral representations not fully addressed in this Agreement. Any prior agreements between or directly involving you and the Company are superseded by this Agreement, provided however, that this Agreement shall not in any way affect, modify, or nullify any prior agreement that you entered into with the Company regarding confidentiality, trade secrets, inventions, or unfair competition, including, without limitations, the Continuing Obligations referenced in Section 10, and in the event of any conflict between this Agreement and any such prior agreement, the agreements will be interpreted to provide the Company with cumulative rights and remedies such that the terms most protective of the Company are enforced. Further, and for the avoidance of doubt, to the extent of any conflict between the terms of this Agreement and any other document concerning severance benefits, the provisions of this Agreement shall prevail. The headings in this Agreement are provided for reference only and shall not affect the substance of this Agreement.

22. Execution. This Agreement may be executed in two or more counterparts, including by electronic delivery, each of which shall be deemed an original, and together, all of which shall constitute one original document. Original signatures that are transmitted by fax or electronic mail shall be considered original signatures under this Agreement. This Agreement is and shall be deemed to be executed under seal.

INTENDING TO BE BOUND, the undersigned have executed this Agreement under seal as of the date written below.

/s/ Steven Ryder Date: March 31, 2026
Employee Signature

RALLYBIO CORPORATION

/s/ Stephen Uden Date: April 8, 2026
By: Stephen Uden, M.D.
Chief Executive 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: May 13, 2026

By: /s/ Stephen Uden

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

Exhibit 31.2

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

I, Jonathan I. Lieber, certify that:

1. I have reviewed this 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: May 13, 2026

By: /s/ Jonathan I. Lieber

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

Exhibit 32.1

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

In connection with the Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending March 31, 2026 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: May 13, 2026

By: /s/ Stephen Uden

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

Exhibit 32.2

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

In connection with the Quarterly Report of Rallybio Corporation (the "Company") on Form 10-Q for the period ending March 31, 2026 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: May 13, 2026

By: /s/ Jonathan I. Lieber

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