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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-42914

MapLight Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2163243**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
800 Chesapeake Drive Redwood City, California	**94063**
(Address of principal executive offices)	**(Zip Code)**

(617) 984-6300
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, par value $0.0001 per share	MPLT	Nasdaq Global Select Market

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 11, 2026, the registrant had 56,207,896 shares of common stock, $0.0001 par value per share, outstanding, of which 53,480,385 shares were Voting Common Stock and 2,727,511 shares were Non-Voting Common Stock.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

MapLight Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 55,568	$ 46,729
Short-term investments	228,512	258,374
Prepaid expenses and other current assets	10,515	19,567
Total current assets	294,595	324,670
Property and equipment, net	722	1,095
Long-term investments	179,333	147,993
Restricted cash	1,074	207
Right-of-use asset	1,445	5,488
Other assets	14	59
Total assets	$ 477,183	$ 479,512
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,964	$ 3,289
Accrued expenses	26,758	12,049
Lease liability - current	1,180	891
Total current liabilities	30,902	16,229
Lease liability - noncurrent	510	4,911
Total liabilities	31,412	21,140
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value per share; 500,000,000 shares authorized at September 30, 2026 and December 31, 2025; 55,669,897 and 44,024,088 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	6	5
Additional paid-in-capital	981,767	819,115
Accumulated other comprehensive loss	(3,006)	(228)
Accumulated deficit	(532,996)	(360,520)
Total stockholders' equity	445,771	458,372
Total liabilities and stockholders' equity	$ 477,183	$ 479,512

The accompanying notes are an integral part of these condensed consolidated financial statements.

MapLight Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 44,208	$ 27,094	$ 151,328	$ 73,726
General and administrative	11,135	4,404	32,067	11,980
Total operating expenses	55,343	31,498	183,395	85,706
Loss from operations	(55,343)	(31,498)	(183,395)	(85,706)
Other income, net:				
Interest income	3,094	1,549	7,915	3,048
Other income, net	633	531	3,004	1,054
Net loss	$ (51,616)	$ (29,418)	$ (172,476)	$ (81,604)
Net loss per share - basic and diluted	$ (0.97)	$ (37.18)	$ (3.60)	$ (105.70)
Weighted-average number of common shares outstanding - basic and diluted	53,100,322	791,127	47,964,806	772,031
Comprehensive loss:				
Net loss	$ (51,616)	$ (29,418)	$ (172,476)	$ (81,604)
Other comprehensive loss:				
Unrealized loss on available-for-sale investments	(2,062)	(4)	(2,778)	(116)
Comprehensive loss	$ (53,678)	$ (29,422)	$ (175,254)	$ (81,720)

The accompanying notes are an integral part of these condensed consolidated financial statements.

MapLight Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Series D Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series A-1 Redeemable Convertible Preferred Stock		Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Deficit
Balance, December 31, 2024	—	$ —	147,325,257	$ 224,992	4,622,496	$ 11,981	45,010,383	$ 51,094	14,946,844	$ 15,963	5,000,000	$ 4,793	761,276	$ —	$ 5,577	$ 163	$ (199,368)	$ (193,628)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	212	—	—	212
Issuance of common stock from exercises of stock options	—	—	—	—	—	—	—	—	—	—	—	—	884	—	5	—	—	5
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(78)	—	(78)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(22,340)	(22,340)
Balance, March 31, 2025	—	$ —	147,325,257	$ 224,992	4,622,496	$ 11,981	45,010,383	$ 51,094	14,946,844	$ 15,963	5,000,000	$ 4,793	762,160	$ —	$ 5,794	$ 85	$ (221,708)	$ (215,829)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	148	—	—	148
Issuance of common stock from exercises of stock options	—	—	—	—	—	—	—	—	—	—	—	—	474	—	3	—	—	3
Issuance of common stock to NeuroSolis, Inc.	—	—	—	—	—	—	—	—	—	—	—	—	26,607	—	496	—	—	496
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(29,845)	(29,845)
Balance, June 30, 2025	—	$ —	147,325,257	$ 224,992	4,622,496	$ 11,981	45,010,383	$ 51,094	14,946,844	$ 15,963	5,000,000	$ 4,793	789,241	$ —	$ 6,441	$ 50	$ (251,553)	$ (245,062)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	125	—	—	125
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of $1,160	210,033,285	198,870	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock from exercises of stock options	—	—	—	—	—	—	—	—	—	—	—	—	18,774	—	183	—	—	183
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(29,418)	(29,418)
Balance, September 30, 2025	210,033,285	$ 198,870	147,325,257	$ 224,992	4,622,496	$ 11,981	45,010,383	$ 51,094	14,946,844	$ 15,963	5,000,000	$ 4,793	808,015	$ —	$ 6,749	$ 46	$ (280,971)	$ (274,176)

The accompanying notes are an integral part of these condensed consolidated financial statements.

MapLight Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2025	44,024,088	$ 5	$ 819,115	$ (228)	$ (360,520)	$ 458,372
Stock-based compensation expense	—	—	9,636	—	—	9,636
Issuance of common stock from exercises of stock options	205	—	1	—	—	1
Settlement of restricted stock units, net of employee tax obligations	1,139,648	—	—	—	—	—
Purchases of common stock under the Employee Stock Purchase Plan	44,981	—	650	—	—	650
Payment of employee tax obligations related to vesting of restricted stock units	—	—	(7,502)	—	—	(7,502)
Unrealized loss on available-for-sale investments	—	—	—	(655)	—	(655)
Net loss	—	—	—	—	(60,668)	(60,668)
Balance, March 31, 2026	45,208,922	$ 5	$ 821,900	$ (883)	$ (421,188)	$ 399,834
Stock-based compensation expense	—	—	8,626	—	—	8,626
Issuance of common stock from exercises of stock options	10,542	—	92	—	—	92
Settlement of restricted stock units	217,403	—	—	—	—	—
Unrealized loss on available-for-sale investments	—	—	—	(61)	—	(61)
Net loss	—	—	—	—	(60,192)	(60,192)
Balance, June 30, 2026	45,436,867	$ 5	$ 830,618	$ (944)	$ (481,380)	$ 348,299
Stock-based compensation expense	—	—	10,255	—	—	10,255
Issuance of common stock and pre-funded warrants in a private placement, net of issuance costs of $10.0 million	9,197,887	1	140,050	—	—	140,051
Issuance of common stock from exercises of stock options	3,133	—	31	—	—	31
Settlement of restricted stock units, net of employee tax obligations	937,832	—	—	—	—	—
Purchases of common stock under the Employee Stock Purchase Plan	94,178	—	813	—	—	813
Unrealized loss on available-for-sale investments	—	—	—	(2,062)	—	(2,062)
Net loss	—	—	—	—	(51,616)	(51,616)
Balance, September 30, 2026	55,669,897	$ 6	$ 981,767	$ (3,006)	$ (532,996)	$ 445,771

The accompanying notes are an integral part of these condensed consolidated financial statements.

MapLight Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (172,476)	$ (81,604)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	444	438
Stock-based compensation expense	28,517	485
Net amortization of premiums and accretion of discounts on investments	(1,955)	(660)
Common stock issued to NeuroSolis, Inc.	—	496
Non-cash lease expense	668	644
Loss on disposal of property and equipment	4	7
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	9,097	(10,774)
Accounts payable	(343)	491
Accrued expenses	5,056	1,775
Operating lease liabilities	(737)	(573)
Deferred grant earnings	—	(2,033)
Net cash used in operating activities	(131,725)	(91,308)
Cash flows from investing activities		
Purchases of short-term and long-term investments	(209,583)	(142,057)
Maturities and redemptions of investments	207,283	61,500
Purchases of property and equipment	(58)	(97)
Net cash used in investing activities	(2,358)	(80,654)
Cash flows from financing activities		
Proceeds from issuance of common stock and pre-funded warrants in a private placement, net of issuance costs	149,704	—
Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs	—	198,870
Payments of deferred financing costs	—	(1,127)
Proceeds from exercises of stock options	124	112
Proceeds from employee stock purchase plan issuances	1,463	—
Payment of employee tax obligations related to vesting of restricted stock units	(7,502)	—
Net cash provided by financing activities	143,789	197,855
Increase in cash, cash equivalents and restricted cash	9,706	25,893
Cash, cash equivalents and restricted cash at beginning of period	46,936	38,460
Cash, cash equivalents and restricted cash at end of period	$ 56,642	$ 64,353
Supplemental disclosure of non-cash investing and financing activities:		
Deferred financing costs included in accounts payable and accrued expenses	$ 9,653	$ 2,325
Derecognition of right-of-use asset and lease liabilities	$ 3,374	$ —
Purchase of property and equipment included in accounts payable and accrued expenses	$ 17	$ —
Proceeds from exercise of stock options included in prepaid expenses and other current assets	$ —	$ 79

The accompanying notes are an integral part of these condensed consolidated financial statements.

MapLight Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of the Business

MapLight Therapeutics, Inc. ("MapLight" or the "Company") was incorporated in November 2018 as Alvarado Therapeutics, Inc., a Delaware corporation. In August 2019, the Company changed its name to MapLight Therapeutics, Inc. The Company is a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system ("CNS") disorders.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for its programs, market acceptance of products, developments related to its competitors, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of intellectual property, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Reverse Stock Split, Initial Public Offering and Concurrent Private Placement

In October 2025, the Company effected a 1-for-16.8 reverse stock split of the Company's common stock. This also resulted in an adjustment to the conversion price for each series of the Company's redeemable convertible preferred stock, to the number of shares of common stock underlying outstanding restricted stock units, and to the exercise prices and number of shares of common stock underlying outstanding stock options. The par value per share and authorized number of shares of the Company's common stock were not adjusted as a result of the reverse stock split. All share and per share information relating to common stock for the nine months ended September 30, 2025 in the accompanying condensed consolidated financial statements and notes thereto has been retroactively adjusted.

In October 2025, the Company closed its initial public offering ("IPO"), pursuant to which the Company issued and sold an aggregate of 16,962,500 shares of its common stock at a price of $17.00 per share for gross proceeds of $288.4 million. The Company received aggregate net proceeds of $261.6 million from the IPO, including the exercise by the underwriters of their option to purchase additional shares, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the IPO, the Company also closed a private placement, in which the Company issued and sold 476,707 shares of its common stock at a price of $17.00 per share (the "Concurrent Private Placement"). The Company received aggregate net proceeds of $7.5 million from the Concurrent Private Placement, after deducting placement agent fees and private placement expenses.

Upon the closing of the IPO, all of the Company's then-outstanding shares of redeemable convertible preferred stock converted into 25,412,974 shares of common stock, of which 2,727,511 shares were non-voting common stock, at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

In August 2026, the Company completed an additional private placement that generated net proceeds of $140.1 million, as described below in Note 8.

Liquidity and Going Concern

The Company's unaudited condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative operating cash flows since inception, and had an accumulated deficit of $533.0 million as of September 30, 2026. The Company expects to continue to generate operating losses for the foreseeable future. The Company's future viability is dependent on its ability to raise additional capital to finance its operations and pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all.

The Company has funded its operations primarily with proceeds from the sale of capital stock. The Company's current operating plans include funding multiple clinical trials for its lead product candidate, ML-007C-MA. Based on its current operating plans and financial position, the Company believes that its existing cash, cash equivalents and investments of $463.4 million will be sufficient to

allow the Company to fund its operations for at least twelve months from the date these condensed consolidated financial statements were issued.

2. Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the accompanying condensed consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2025. There have been no material changes to the Company's accounting policies during the nine months ended September 30, 2026.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet at September 30, 2026, the condensed consolidated statements of operations and comprehensive loss and the statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2026 and 2025, and the statements of cash flows for the nine months ended September 30, 2026 and 2025 are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of its financial position at September 30, 2026, the results of its operations for the three and nine months ended September 30, 2026 and 2025, its statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2026 and 2025 and its cash flows for the nine months ended September 30, 2026 and 2025. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2026 and 2025 are also unaudited. The results for the nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026 or for any other subsequent interim period. The accompanying condensed consolidated balance sheet at December 31, 2025 was derived from the audited annual financial statements; however, certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been omitted from the unaudited interim condensed consolidated financial statements, as is permitted by such rules and regulations. The condensed consolidated financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2025, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025.

Recently Issued But Not Yet Adopted Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*: *Disaggregation of Income Statement Expenses* (“ASU 2024-03”) and in January 2025, the FASB issued ASU No. 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date* (“ASU 2025-01”). ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01, is effective for public companies for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is still evaluating the impact on its disclosures in future years as a result of the adoption of ASU 2024-03.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which clarifies the applicability of interim reporting guidance, the form and content of interim financial statements and interim disclosure requirements. The amendments are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting the amendments on its condensed consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-12, *Codification Improvements* ("ASU 2025-12"). ASU 2025-12 addresses suggestions received from stakeholders regarding the Accounting Standards Codification ("ASC") and makes incremental improvements to U.S. GAAP by clarifying, correcting errors in, or otherwise improving a variety of topics. ASU 2025-12 is effective for the Company for annual reporting periods beginning after December 15, 2026, and interim periods within those annual periods, with early adoption permitted. The amendments to ASC 260, Earnings Per Share, are required to be applied retrospectively, and all other amendments may be applied prospectively or retrospectively. The Company is currently evaluating the impact of adopting ASU 2025-12 on its condensed consolidated financial statements and related disclosures.

3. Investments

The following tables summarize the amortized cost and estimated fair value of the Company's available-for-sale investments that were included in short-term investments and long-term investments as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. Treasury securities	$ 93,233	$ —	$ (438)	$ 92,795
Commercial paper	33,833	—	(22)	33,811
Corporate debt securities	92,414	—	(526)	91,888
Certificates of deposit	10,030	—	(12)	10,018
Long-term investments:				
Corporate debt securities	181,341	—	(2,008)	179,333
	$ 410,851	$ —	$ (3,006)	$ 407,845

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. Treasury securities	$ 95,550	$ 72	$ (13)	$ 95,609
Commercial paper	137,101	22	(19)	137,104
Corporate debt securities	25,680	18	(37)	25,661
Long-term investments:				
U.S. Treasury securities	73,072	—	(60)	73,012
Corporate debt securities	75,192	—	(211)	74,981
	$ 406,595	$ 112	$ (340)	$ 406,367

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the condensed consolidated balance sheets and are not included in the tables above. As of September 30, 2026 and December 31, 2025, all short-term investments had contractual maturities within one year.

The aggregate fair value of available-for-sale securities held by the Company that were in an unrealized loss position for less than 12 months as of September 30, 2026 was $403.8 million and the unrealized loss associated with available-for-sale securities was $3.0 million. There were no available-for-sale securities in a continuous unrealized loss position for greater than 12 months. The Company evaluated its securities for potential impairment and considered the decline in market value to be primarily attributable to current economic and market conditions. Additionally, the Company does not intend to sell the investments that are in an unrealized loss position and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at the time of maturity. Based on its evaluation, including the nature of the securities, current economic and market conditions, and the lack of a significant change in credit risk for these investments, the Company determined that the unrealized losses were not attributable to credit losses. Accordingly, no allowances for credit losses were recorded as of September 30, 2026 or December 31, 2025.

4. Fair Value Measurements

The following tables summarize the Company's cash equivalents and investments (in thousands):

	Fair Value Measurements at September 30, 2026			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 27,964	$ 27,964	$ —	$ —
Short-term investments:				
U.S. Treasury securities	92,795	92,795	—	—
Commercial paper	33,811	—	33,811	—
Corporate debt securities	91,888	—	91,888	—
Certificates of deposit	10,017	—	10,017	—
Long-term investments:				
Corporate debt securities	179,333	—	179,333	—
	$ 435,808	$ 120,759	$ 315,049	$ —

	Fair Value Measurements at December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 30,833	$ 30,833	$ —	$ —
Short-term investments:				
U.S. Treasury securities	95,609	95,609	—	—
Commercial paper	137,104	—	137,104	—
Corporate debt securities	25,661	—	25,661	—
Long-term investments:				
U.S. Treasury securities	73,012	73,012	—	—
Corporate debt securities	74,981	—	74,981	—
	$ 437,200	$ 199,454	$ 237,746	$ —

The Company classifies its money market funds and U.S. Treasury securities as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its commercial paper and corporate debt securities as Level 2 assets under the fair value hierarchy as these assets have been valued using information obtained through a third-party pricing service as of the balance sheet date, using observable market inputs that may include trade information, broker or dealer quotes, bids, offers, or a combination of these data sources.

During the nine months ended September 30, 2026 and the year ended December 31, 2025, there were no transfers between levels.

The Company uses the carrying amounts of its prepaid expenses and other current assets, restricted cash, other assets, accounts payable and accrued expenses to approximate their fair values due to the short-term nature of these items.

5. Accrued Expenses

Accrued expenses of the Company consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Research and development	$ 8,211	$ 4,829
Employee compensation	7,416	6,162
Legal services	728	537
Private placement	9,653	—
Other	750	521
	$ 26,758	$ 12,049

6. Leases

The Company leases office and laboratory space, and the leases are classified as operating leases on the condensed consolidated balance sheets.

The Company has a lease for office and laboratory space in Redwood City, California. The lease includes a mutual early termination option that permits either party to terminate the lease by providing at least fifteen months' prior written notice. In June 2026, the Company exercised the early termination option by providing the required notice to the lessor. As a result, the end of the term of the lease changed from June 2031 to September 2027. During the nine months ended September 30, 2026, the Company derecognized a right-of-use asset and lease liabilities of $3.4 million due to the change to the term of this lease.

The Company has a lease for office space in Burlington, Massachusetts, with a term that continues to May 2029, and with an option to extend the term for an additional five years.

In June 2026, the Company entered into a lease for office and laboratory space in South San Francisco, California. The lease term will be seven years from the lease commencement date and includes an option to extend the lease for an additional five years. The lease has not yet commenced, and accordingly, as of September 30, 2026, no right-of-use asset or lease liability has been recognized and no lease expense has been recorded related to this lease. The Company expects the lease to commence in May 2027, subject to completion of the landlord's tenant improvements and delivery of the premises.

The following table summarizes the presentation of the Company's operating leases on its condensed consolidated balance sheets (in thousands):

	Balance Sheet Classification	September 30, 2026	December 31, 2025
Assets:			
Operating lease assets	Right-of-use asset	$ 1,445	$ 5,488
Liabilities:			
Current:			
Operating lease liabilities	Lease liability - current	1,180	891
Noncurrent:			
Operating lease liabilities	Lease liability - non-current	510	4,911
Total lease liabilities		$ 1,690	$ 5,802

The components of lease expense included in research and development expenses and general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	2026	2025	2026	2025
Operating lease costs	$ 264	$ 346	$ 928	$ 1,037
Variable lease costs	154	56	462	218
	$ 418	$ 402	$ 1,390	$ 1,255

As of September 30, 2026 and December 31, 2025, the weighted-average remaining lease term for operating leases was 1.8 years and 5.2 years, respectively, and the weighted-average discount rate was 9.5% and 8.7%, respectively. During the three months ended September 30, 2026 and 2025, cash paid for amounts included in the measurement of lease liabilities was $0.3 million. During the nine months ended September 30, 2026 and 2025, cash paid for amounts included in the measurement of lease liabilities was $1.0 million.

Future minimum annual lease commitments under the Company's operating leases, excluding the lease in South San Francisco for which the term has not yet commenced, were as follows as of September 30, 2026 (in thousands):

Year Ended December 31,	Amount
2026 (remaining 3 months)	$ 338
2027	1,022
2028	334
2029	140
Total lease payments	1,834
Less: imputed interest	(144)
Present value of operating lease liabilities	$ 1,690

7. Redeemable Convertible Preferred Stock

Prior to the IPO in October 2025, the Company had authorized 603,469,745 shares of voting redeemable convertible preferred stock, of which it had designated 5,000,000 shares as Series A Preferred Stock, 14,946,844 shares as Series A-1 Preferred Stock, 45,010,383 shares as Series B Preferred Stock, 147,325,527 shares as Series C Preferred Stock and 391,186,991 shares as Series D Preferred Stock ("Series D"), and had authorized 4,622,496 shares of non-voting redeemable convertible preferred stock, of which it had designated 4,622,496 shares as Series B-1 Preferred Stock (collectively, the "Preferred Stock").

On July 18, 2025, the Company entered into a Series D Preferred Stock Purchase Agreement with certain investors. During the year ended December 31, 2025, the Company issued a total of 210,033,285 shares of Series D to investors at a purchase price of $0.95223 per share for gross proceeds of $200.0 million. The Company incurred issuance costs of $1.2 million in connection with the completion of the Series D financing.

In connection with the IPO in October 2025, all outstanding shares of the Company's Preferred Stock automatically converted into an aggregate of 25,412,974 shares of the Company's common stock, of which 2,727,511 shares were non-voting common stock.

8. Common Stock

As of September 30, 2026 and December 31, 2025, the Company's amended and restated certificate of incorporation authorized the Company to issue 500,000,000 shares of common stock with a par value of $0.0001 per share, of which 497,272,489 shares were designated as voting common stock and 2,727,511 shares were designated as non-voting common stock. Unless otherwise indicated or the context requires otherwise, all references to “common stock” in these notes refer to the Company’s voting common stock. As of September 30, 2026 and December 31, 2025, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

The holders of the voting common stock have the right to one vote for each share of voting common stock held on each matter properly submitted for approval at each meeting of stockholders. Shares of non-voting common stock have no voting rights. Each share of the Company’s non-voting common stock may be converted at any time into one share of voting common stock at the option of its holder by providing written notice to the Company, provided that the holder will be prohibited from converting non-voting common stock into voting common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company’s voting common stock then issued and outstanding, which percentage may be increased to such other percentage not to exceed 19.99% upon 61 days’ notice to the Company or decreased at any time upon notice to the Company. Dividends may be paid when, as and if declared by the Board of Directors of the Company (the "Board"), subject to any preferential dividend rights of any series of preferred stock that may be outstanding. As of September 30, 2026, no cash dividends had been declared or paid.

As of September 30, 2026 and December 31, 2025, the Company had reserved the following shares of voting common stock:

Reserved Voting Common Stock	September 30, 2026	December 31, 2025
Common stock incentive awards outstanding	8,744,304	9,142,493
Common stock issuable upon exercise of pre-funded warrants	3,983,168	—
Reserved for conversion of non-voting common stock	2,727,511	2,727,511
Common stock available for future grant under the 2025 Equity Incentive Plan	2,229,491	589,586
Common stock available for future issuance under the Employee Stock Purchase Plan	751,081	450,000
	18,435,555	12,909,590

August 2026 Private Placement

On August 13, 2026, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold and issued in a private placement transaction (the “2026 Private Placement”) (i) 9,197,887 shares of the Company’s common stock, and (ii) with respect to certain institutional investors, pre-funded warrants to purchase 3,983,168 shares of common stock in lieu of shares of common stock. The purchase price per share of common stock was $11.38, and the purchase price per pre-funded warrant was $11.3799 per share of common stock underlying the pre-funded warrant. The 2026 Private Placement closed on August 14, 2026, and the Company received net proceeds of approximately $140.1 million, after deducting placement agent fees and other offering expenses of $10.0 million.

The pre-funded warrants have a per share exercise price of $0.0001, subject to proportional adjustments in the event of stock splits or combinations or similar events. The pre-funded warrants will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of shares of common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation; provided, however, that a holder that holds less than 20% of the common stock prior to such exercise may increase or decrease the beneficial ownership limitation by giving notice to the Company, but not to any percentage in excess of 19.99%, or, for Catalyst4, Inc. ("Catalyst"), 49.99%, provided that any increase will not be effective until the 61st day after such notice.

With respect to Catalyst, which purchased both shares of common stock and pre-funded warrants in connection with the offering, the Company allocated the gross proceeds between the common stock and pre-funded warrants based on their relative fair values on the issuance date. The other investors purchased either common stock or pre-funded warrants, and therefore no allocation of proceeds was required.

The pre-funded warrants are immediately exercisable, are freestanding instruments indexed to the Company’s common stock and meet the criteria for equity classification under ASC 815-40. Accordingly, the Company recorded the proceeds from the pre-funded warrants, net of allocated issuance costs, in additional paid-in capital. As of September 30, 2026, none of the pre-funded warrants had been exercised.

Registration Rights Agreement

In connection with the 2026 Private Placement, the Company entered into a registration rights agreement with the investors (the “Registration Rights Agreement”), under which the Company agreed to register for resale the shares of common stock issued in the 2026 Private Placement and the shares of common stock issuable upon exercise of the pre-funded warrants. If the Company fails to meet specified filing or effectiveness deadlines or to maintain the effectiveness of the registration statement, subject to certain allowable delays, it must pay the investors liquidated damages in cash, not to exceed 5% of the aggregate purchase price (approximately $7.5 million). In September 2026, the registration statement on Form S-1 registering the resale of the shares of common stock issued in the 2026 Private Placement and the shares of common stock issuable upon exercise of the pre-funded warrants was declared effective by the SEC.

The Company accounts for the Registration Rights Agreement as a registration payment arrangement under ASC 825-20.The resale registration statement was declared effective by the SEC in September 2026 within the required periods. The Company has concluded that payment of liquidated damages is not probable and has not recorded a liability as of September 30, 2026.

9. Stock-Based Compensation

2019 Equity Incentive Plan

In February 2019, the Company adopted the 2019 Equity Incentive Plan (the "2019 Plan"). All employees, directors, and consultants were eligible to be granted stock options, restricted stock and restricted stock units ("RSUs") under the terms of the 2019

Plan. Upon the effectiveness of the 2025 Equity Incentive Plan ("2025 Plan"), the 2019 Plan was terminated and no further grants were made under the 2019 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2019 Plan.

All stock option grants were non-statutory stock options except option grants to employees that were intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options could not have been granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the Board at its sole discretion. Nonqualified stock options could have been granted at an exercise price established by the Board at its sole discretion (which had not been less than fair market value on the date of grant) and the vesting periods could have varied. Vesting periods were generally four years and were determined by the Board. Stock options became exercisable as they vested. Options granted under the 2019 Plan expire no more than ten years from the date of grant.

2025 Equity Incentive Plan

In October 2025, the Board adopted and approved, and the Company's stockholders approved, the 2025 Plan, which became effective immediately prior to the execution of the underwriting agreement related to the Company's IPO. The 2025 Plan allows the Company to make equity-based incentive awards to its employees, directors, and consultants. The 2025 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, RSUs and other stock-based awards. Initially, up to 11,500,000 shares were reserved for issuance under the 2025 Plan, which is the sum of: (i) 4,300,000 new shares, plus (ii) up to 7,200,000 shares of common stock subject to awards granted under the 2019 Plan that, after the effective date of the 2025 Plan, expire or otherwise terminate without having been exercised in full, are forfeited or repurchased. The number of shares of common stock reserved for issuance under the 2025 Plan automatically increased on January 1, 2026 by 2,201,204 shares and will increase each January 1 thereafter through January 1, 2035, by five percent of the aggregate number of shares of voting common stock and non-voting common stock issued and outstanding and shares of common stock issuable upon exercise of outstanding pre-funded warrants, if any, as of the immediately preceding December 31 or such lesser number of shares of common stock as determined by the Board. Options granted under the 2025 Plan expire no more than ten years from the date of grant.

The shares of common stock underlying any awards under the 2025 Plan and the 2019 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2025 Plan.

As of September 30, 2026, there were 2,229,491 shares of common stock available for future grant under the 2025 Plan.

2025 Employee Stock Purchase Plan

In October 2025, the Board adopted and approved, and the Company's stockholders approved, the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which became effective immediately prior to the execution of the underwriting agreement related to the Company's IPO. A total of 450,000 shares of common stock were initially reserved and available for issuance under the 2025 ESPP. The number of shares of common stock that may be issued under the 2025 ESPP automatically increased on January 1, 2026 by 440,240 shares and will increase each January 1 thereafter through January 1, 2035, by the lesser of (i) one percent of the aggregate number of shares of voting common stock and non-voting common stock issued and outstanding and shares of common stock issuable upon exercise of outstanding pre-funded warrants, if any, as of the immediately preceding December 31 and (ii) 900,000 shares of common stock, or such lesser number of shares of common stock as determined by the Board. As of September 30, 2026, 751,081 shares of common stock were reserved and available for issuance under the 2025 ESPP.

During the nine months ended September 30, 2026, 139,159 shares of the Company's common stock were issued under the 2025 ESPP. During the three and nine months ended September 30, 2026, stock-based compensation expense recognized related to the 2025 ESPP was $0.4 million and $0.7 million.

Stock Options

A summary of the stock option activity of the Company during the nine months ended September 30, 2026 is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2025	3,865,381	$ 14.30	8.85	$ 12,625
Granted	1,196,309	17.34		
Exercised	(13,880)	8.97		$ 233
Cancelled	(240,417)	16.83		
Outstanding as of September 30, 2026	4,807,393	$ 14.95	8.44	$ 4,223
Exercisable as of September 30, 2026	877,850	$ 5.38	4.93	$ 4,219

Stock options generally vest over four years, with 25% vesting approximately one year after grant and 75% vesting in equal monthly installments thereafter, subject to the recipient's continued service with the Company through each vesting date. The fair value of options vested was $0.1 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively. The fair value of options vested was $0.3 million and $0.5 million for the nine months ended September 30, 2026 and 2025, respectively. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2026 was $13.76. During the nine months ended September 30, 2025, the Company granted no stock options. As of September 30, 2026, unrecognized stock-based compensation expense related to unvested stock options was $41.8 million, which is expected to be recognized over a weighted-average vesting period of 3.03 years.

RSUs

RSUs generally vest over four years, with 25% vesting approximately one year after grant and 75% vesting in equal quarterly installments thereafter, subject to the recipient's continued service with the Company through each vesting date. RSUs issued under the 2025 Plan include a service condition.

RSUs issued under the 2019 Plan include both service and performance conditions. The performance condition required a liquidity event in order to vest, which was satisfied in connection with the IPO in October 2025. The service condition needs to be satisfied on or before the expiration date (the earlier of seven years after the grant date or termination of employment), or else the RSUs will not vest and will be forfeited.

A summary of the RSU activity of the Company during the nine months ended September 30, 2026 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2025	5,277,112	$ 13.08
Granted	433,182	16.49
Vested	(1,362,963)	12.61
Cancelled	(410,420)	12.62
Outstanding as of September 30, 2026	3,936,911	$ 13.67

During the nine months ended September 30, 2026 and 2025, 1,362,963 and no RSUs vested. As of September 30, 2026, unrecognized stock-based compensation expense related to RSUs was $45.2 million, which is expected to be recognized over a weighted-average vesting period of 2.45 years.

Stock-Based Compensation Expense

Stock-based compensation expense of the Company is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 5,910	$ 84	$ 17,013	$ 331
General and administrative	4,345	41	11,504	154
	$ 10,255	$ 125	$ 28,517	$ 485

10. Net Loss Per Share

Basic and diluted net loss per share of the Company was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (51,616)	$ (29,418)	$ (172,476)	$ (81,604)
Denominator:				
Weighted-average number of common shares outstanding - basic and diluted	53,100,322	791,127	47,964,806	772,031
Net loss per share - basic and diluted	$ (0.97)	$ (37.18)	$ (3.60)	$ (105.70)

The Company issued and sold pre-funded warrants in August 2026 (as described in Note 8). The shares of common stock underlying the pre-funded warrants are included in the calculation of basic and diluted net loss per share because they are considered shares issuable for little or no consideration under ASC 260, Earnings Per Share.

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following shares from the computation of diluted net loss per share as of September 30, 2026 and 2025 because including them would have had an anti-dilutive effect:

	September 30,	
	2026	2025
Options to purchase common stock	4,807,393	933,010
RSUs	3,936,911	6,212,236
Redeemable convertible preferred stock	—	25,412,974
	8,744,304	32,558,220

11. Commitments and Contingencies

Legal Proceedings

The Company may, from time to time, be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of September 30, 2026, and no material legal proceedings are currently pending or, to the best of the Company's knowledge, threatened.

Contractual Obligations

NeuroSolis, Inc. asset purchase agreement

Pursuant to the asset purchase agreement that the Company entered into with NeuroSolis, Inc. ("NeuroSolis") to acquire its proprietary M_1/M_4 agonist molecules and associated intellectual property, the Company has an obligation to potentially issue up to an aggregate of 62,083 shares of the Company's common stock, contingent upon the occurrence of specified development and regulatory milestones prior to certain specified dates. As of September 30, 2026, the Company has made upfront and development milestone payments of $150,000 to NeuroSolis. In June 2025, the Company issued 26,607 shares of the Company's common stock to NeuroSolis

upon the initiation of a Phase 2 clinical trial for ML-007C-MA. As of September 30, 2026, it is uncertain whether the remaining development and regulatory milestone would occur prior to its specified date and whether the additional 35,476 shares of the Company's common stock would be required to be issued.

Michael J. Fox Foundation grant agreements

Between February 2020 and August 2022, the Company executed four grant agreements (the "Grants") with the Michael J. Fox Foundation for the purpose of researching Parkinson's disease. The Grants consisted of two-year and three-year research programs totaling $25.7 million. As of December 31, 2025, all funds were received and the balance of deferred grant earnings was zero.

The Grants were payable in installments over the term of the grant according to certain research milestones and progress reports. Funds received for the purchase of property and equipment were accounted for as a reduction to the carrying value of the corresponding asset. Funds received for the reimbursement of expenses incurred related to research and development were accounted for as a reduction to the associated expense. Funds received prior to a corresponding asset purchase or incurred expense were recorded as a deferred grant liability on the condensed consolidated balance sheets.

During the three and nine months ended September 30, 2025, the Company recognized $1.2 million and $2.0 million of grant earnings.

The Company may be obligated to make future payments under the Grants, restricted to two times the grant awards received, contingent upon certain net product sales. As of September 30, 2026, the Company was unable to estimate the timing or likelihood of generating future product sales.

Universities and other third parties

The Company may be obligated to make future payments, in addition to nominal annual maintenance fees, under license and collaboration agreements with Stanford University, other universities and other third parties upon the occurrence of future events such as the Company's achievement of specified regulatory and commercial milestones or royalties on net sales. As of September 30, 2026, the Company was unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Guarantees

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

As of September 30, 2026, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been recorded.

License Agreement

In November 2024, the Company entered into a license agreement with Vanderbilt University ("Vanderbilt") (the "Vanderbilt Agreement"), pursuant to which the Company has been granted an exclusive, royalty-bearing, worldwide sublicensable license to develop, make, have made, use, offer for sale, sell, import and exploit certain compounds and licensed products, and a non-exclusive, royalty-bearing, worldwide, sublicensable license to use licensed know-how and tool compounds to develop, make, have made, use, offer for sale, sell, import and exploit certain compounds and licensed products.

As initial consideration for the license, the Company made a one-time, non-creditable, non-refundable upfront payment of $0.3 million upon the execution of the agreement. The Company also made a one-time, non-creditable, non-refundable payment of $0.3 million upon the execution of the agreement for the reimbursement of past patenting costs incurred by Vanderbilt. As additional consideration for the license, the Company agreed to pay to Vanderbilt aggregate development and commercial milestone payments of up to $52.4 million. The Company is also required to pay royalties at a low single digit percentage based on annual net sales of licensed products sold by the Company. Such royalty payments are subject to reductions if sales are made in calendar quarters during which there is no valid claim or no market exclusivity for a licensed product. Any such royalties are payable on a country-by-country and licensed product-by-licensed product basis until the expiration of the last to expire valid claim of the licensed patents.

In September 2026, the Company entered into an amendment to the Vanderbilt Agreement, pursuant to which the Company agreed to make a one-time payment of $0.4 million and revised certain development milestones, milestone payment obligations, sublicensing terms and development diligence requirements. Under the amended agreement, the Company may be required to make aggregate development and commercial milestone payments of up to $52.0 million, including $0.5 million upon the earlier of completion of certain IND-enabling studies or termination or expiration of the agreement. The amendment also revised the Company's obligations to share sublicensing revenue with Vanderbilt, with applicable percentages ranging from 2% to 50% depending on the stage of development at which a sublicense is granted.

No milestone payments or royalties were paid during the three months ended September 30, 2026 under the Vanderbilt Agreement. As of September 30, 2026, the Company had accrued $0.4 million of expenses owed in connection with the amendment to the Vanderbilt Agreement, which established revised milestone payment obligations. This amount is included in accrued expenses on the condensed consolidated balance sheets and was paid in October 2026.

12. Related Party Transactions

Stellaromics, Inc.

In October 2023, the Company entered into an Assignment and Assumption Agreement (the "Stellaromics Agreement") with Stellaromics, Inc. ("Stellaromics"), an entity focused on developing and commercializing a proprietary three-dimensional transcriptomic device inclusive of a confocal, probes, operating software and sample analysis software, pursuant to which, in exchange for contributing an exclusive worldwide license for STARmap, a three-dimensional intact tissue sequencing, imaging and analysis technology, the Company received 9.8% of the capital stock of Stellaromics at the time of the closing. As of September 30, 2026, the Company held approximately 2.9% of the outstanding stock of Stellaromics.

Prior to entering into the Stellaromics Agreement, Christopher A. Kroeger, M.D., the Company's Chief Executive Officer, was designated to be a director on the board of directors of Stellaromics. Dr. Kroeger is also an equity holder of Stellaromics. Dr. Kroeger's position on the board of directors of Stellaromics is determined by the stockholders holding a majority of the shares of common stock and preferred stock outstanding of Stellaromics. The Company does not have contractual rights to nominate any members to the Stellaromics board of directors.

In October 2023, Catalyst became the largest stockholder of Stellaromics, holding a minority interest of its outstanding capital stock. As of September 30, 2026, Catalyst holds a controlling interest of the outstanding capital stock of Stellaromics. Catalyst is also the largest stockholder of the Company, with a minority equity ownership interest of the Company's outstanding shares as of September 30, 2026 and December 31, 2025.

The Company has significant influence over, but does not control, Stellaromics through its noncontrolling representation on Stellaromics' board of directors and the Company's equity interest in Stellaromics. The Company determined that Stellaromics is a variable interest entity because it does not have sufficient equity at risk to finance its operations without additional subordinated financial support. The Company is not the primary beneficiary as it does not have the power to direct activities that most significantly impact Stellaromics' economic performance. Accordingly, the Company does not consolidate the financial statements of Stellaromics and accounts for its investment using the equity method of accounting. The determination of whether an entity is a variable interest entity and whether the Company is the primary beneficiary of a variable interest entity is based upon the facts and circumstances and requires significant judgments such as whether the entity is a variable interest entity and whether the Company is the primary beneficiary of the entity either individually or via a related party group. The Company's maximum exposure to loss due to its involvement with Stellaromics is the carrying value of the investment. As of December 31, 2024, the carrying value of the investment was $0, and no further losses will be recorded because the Company does not have any obligation to fund future losses.

Advisor Agreement

In February 2019, the Company entered into an advisor agreement with a member of the Board, pursuant to which the Board member received monthly payments in exchange for his service on the Company's scientific advisory board. During the three and nine months ended September 30, 2025, the Company recorded a de minimis amount of research and development expense relating to the Board member's service on the Company's scientific advisory board. As a result of the compensation the director was to earn for service on the Board, the advisor agreement was amended, effective January 1, 2026, pursuant to which the director would not receive monetary compensation for providing services under the advisor agreement.

August 2026 Private Placement

In August 2026, certain existing stockholders of the Company that are considered related parties participated in the 2026 Private Placement. Catalyst, a greater than 5% stockholder of the Company, purchased 4,400,000 shares of common stock and pre-funded warrants to purchase 2,928,686 shares of common stock at an aggregate purchase price of approximately $83.4 million. In addition, Forbion Growth Opportunities Fund III Coöperatief U.A., an entity affiliated with a member of the Company's Board of Directors and a greater than 5% stockholder, purchased 755,711 shares of common stock at an aggregate purchase price of approximately $8.6 million. The aggregate proceeds received from these related parties were approximately $92.0 million.

13. Segment Information

The Company manages its operations as a single reportable segment focused on the research and development of product candidates. The accounting policies of the single reportable segment are identical to those described in Note 2 of the Company's audited consolidated financial statements for the year ended December 31, 2025. The chief operating decision maker, who manages the Company's operations on a consolidated basis, assesses performance for the reportable segment using consolidated net loss to monitor budget versus actual results and to determine how to effectively allocate the Company's resources. The measure of segment assets is reported on the condensed consolidated balance sheets as total consolidated assets. The following table presents certain financial data for the Company's reportable segment for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Clinical trial expenses	$ 15,585	$ 11,915	$ 61,121	$ 29,874
Employee-related research and development expenses	18,271	7,043	51,100	21,050
Chemistry, manufacturing and controls expenses	5,128	4,175	17,876	11,728
Preclinical program expenses	4,500	2,792	18,316	7,042
Other research and development expenses	724	1,169	2,915	4,032
Employee-related general and administrative expenses	7,177	1,904	19,941	5,866
Professional fees and other general and administrative expenses	3,958	2,500	12,126	6,114
Other segment items[(1)]	(3,727)	(2,080)	(10,919)	(4,102)
Net loss	$ 51,616	$ 29,418	$ 172,476	$ 81,604

(1) Other segment items include interest income and other income, net.

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 included elsewhere in this Quarterly Report and with our audited consolidated financial statements and related notes in our Annual Report on Form 10-K for the year ended December 31, 2025. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, future results of operations and financial position, and our objectives for future operations, includes forward-looking statements that involve risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "might," "intend," "target," "ongoing," "project," "estimate," "believe," "predict," "potential," "continue," the negative of these terms or other similar expressions intended to identify statements about the future. As a result of many factors, including those factors set forth in the section entitled "Risk Factors" of this Quarterly Report, 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 or set forth elsewhere in this Quarterly Report.

Overview

We are a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system, or CNS, disorders. We were founded by globally recognized leaders in psychiatry and neuroscience research to address the lack of circuit-specific pharmacotherapies available for patients. Our discovery platform holds the potential to fill this void by identifying neural circuits causally linked to disease and targeting those circuits for therapeutic modulation. We believe our deep understanding of these causal links between the modulation of defined neural circuits and the resulting changes in disease-specific behaviors will enable us to develop therapeutics that can deliver efficacy, safety, tolerability and ease-of-use advantages to patients and prescribers.

Our lead product candidate, ML-007C-MA, is a fixed-dose combination of an M_1/M_4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic, or PAC, which we are initially developing for the treatment of schizophrenia and Alzheimer's disease psychosis, or ADP. ML-007C-MA is designed to activate both M_1 and M_4 muscarinic receptors centrally to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects. ML-007 alone, co-administered or co-formulated with the PAC has been evaluated in four Phase 1 trials, with a total of 270 healthy participants enrolled and more than 1,500 doses of ML-007 administered. Based on our clinical and preclinical data, we believe that ML-007C-MA has demonstrated the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding cerebrospinal fluid, or CSF, exposures expected to result in improvement across key symptom domains. In July 2026, we announced positive topline results from ZEPHYR, a Phase 2 trial evaluating ML-007C-MA for the treatment of schizophrenia. Based on the results of ZEPHYR, we intend to engage with the U.S. Food and Drug Administration, or FDA, in an end-of-Phase 2 meeting to discuss the path forward for ML-007C-MA in schizophrenia, including the design of a Phase 3 trial which, together with ZEPHYR, would be intended to support an initial New Drug Application, or NDA, submission. We have begun planning and site identification for this additional, confirmatory trial.

We are also conducting VISTA, a Phase 2 trial evaluating ML-007C-MA for the treatment of ADP, and we expect to report topline results in the second half of 2027. In December 2025, ML-007C-MA was granted Fast Track designation by the FDA, for the treatment of hallucinations and delusions associated with ADP.

Our second clinical stage product candidate, ML-004, is a $5\text{-HT}_{1B/1D}$ agonist that we are developing for the treatment of social communication deficit and/or irritability in autism spectrum disorder, or ASD. In June 2026, we announced topline results from IRIS, a Phase 2 trial evaluating the efficacy, safety and tolerability of ML-004 in adults and adolescents with ASD. Based on the results of IRIS, we intend to engage with the FDA, in an end-of-Phase 2 meeting to determine the next steps for development of ML-004 in irritability associated with ASD, after which we intend to evaluate the path forward for ML-004, including potential strategic collaborations and/or funding alternatives.

Since our inception in 2018, we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support our operations. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock, and most recently, with net proceeds from our initial public offering, or IPO, and our concurrent private placement, or Concurrent Private Placement, and our August 2026 private placement, or the 2026 Private Placement, discussed below.

We have incurred significant net losses since inception. Our net losses for the nine months ended September 30, 2026 and 2025 were $172.5 million and $81.6 million, respectively. As of September 30, 2026, we had an accumulated deficit of $533.0 million. We expect to continue to incur significant expenses and net losses for the foreseeable future as we advance our current and future product

candidates through preclinical and clinical development, seek regulatory approval for such product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, expand our infrastructure, scale up production capabilities and operate as a public company.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities, initially in the United States.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as collaboration agreements, strategic alliances and licensing agreements. We may be unable to raise additional funds or enter into such other agreements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

At this time, due to the inherently unpredictable nature of clinical and preclinical development and given the current stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current or future product candidates, if at all. For the same reasons, we are also unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or sustain profitability on a continuing basis, then we may be unable to raise additional capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

As of September 30, 2026, we had cash, cash equivalents and investments of $463.4 million. Based on our current operational plans and assumptions, we expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. If we are unable to raise sufficient funding, we may be unable to continue to operate in the long term. See "Liquidity and Capital Resources - Plan of Operation and Future Funding Requirements" below.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates and our research activities and include:

- the salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- the expenses incurred under agreements with contract research organizations, or CROs;
- the costs of outside consultants, including their fees and travel expenses;

- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- the costs associated with clinical trials and preclinical studies; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific activities. Payments for these activities are based on the terms of the related agreements, which may differ from the timing of costs incurred, and those differences, if any, are reflected in our condensed consolidated financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs and therefore we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate and conduct clinical trials.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. We cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. There are numerous risks and uncertainties associated with the duration and cost of successfully developing product candidates, which can vary significantly, including:

- successful and timely completion of preclinical studies;
- initiation of and successful patient enrollment in, and completion of, clinical trials on a timely basis;
- gaining agreement on the design, endpoints and implementation of preclinical studies and clinical trials with the FDA, or any comparable foreign regulatory authority;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting future clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's benefit risk assessment for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- effectively competing with other therapies available on the market or in development; and
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates may significantly change the costs and timing associated with the development of those product candidates and we may never succeed in achieving regulatory approval for any of our product candidates. As a result of these uncertainties, we are unable to forecast the duration and completion costs of our research and development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued clinical development efforts, research and development activities, manufacturing activities and related expansion of our operations. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of Securities and Exchange Commission, or SEC, and the listing standards of the Nasdaq Stock Market LLC, or Nasdaq, director and officer insurance premiums and investor relations costs.

Other Income, Net

Interest Income

Interest income consists of interest income earned on our cash, cash equivalents and investments.

Other Income, Net

Other income, net consists primarily of the amortization of premiums and accretion of discounts to maturity for available-for-sale investments.

Income Taxes

Since our inception, we have not recorded income tax benefits for the net operating losses incurred or the research and development tax credits generated in each year due to the uncertainty of realizing a benefit from those items. As of December 31, 2025, we had U.S. federal and state net operating loss carryforwards of $96.6 million and $13.1 million, respectively, which may be available to offset future taxable income. The federal net operating loss carryforwards do not expire, but may only be used to offset 80% of annual taxable income. The state net operating loss carryforwards expire beginning in 2039. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $13.3 million and $0.2 million, respectively.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 44,208	$ 27,094	$ 17,114
General and administrative	11,135	4,404	6,731
Total operating expenses	55,343	31,498	23,845
Loss from operations	(55,343)	(31,498)	(23,845)
Other income, net:			
Interest income	3,094	1,549	1,545
Other income, net	633	531	102
Net loss	$ (51,616)	$ (29,418)	$ (22,198)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Clinical trial expenses	$ 15,585	$ 11,915	$ 3,670
Employee-related expenses	18,271	7,043	11,228
Chemistry, manufacturing and controls expenses	5,128	4,175	953
Preclinical program expenses	4,500	2,792	1,708
Other expenses	724	1,169	(445)
	$ 44,208	$ 27,094	$ 17,114

Research and development expenses were $44.2 million for the three months ended September 30, 2026, compared to $27.1 million for the three months ended September 30, 2025. The increase in research and development expenses of $17.1 million was primarily due to ongoing advancement of our product candidates, including an increase of $11.2 million in employee-related expenses, $5.8 million of which was stock-based compensation expense, an increase of $3.7 million in clinical trial expenses and an increase of $1.7 million in preclinical program expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Employee-related expenses	$ 7,177	$ 1,904	$ 5,273
Professional fees and other expenses	3,958	2,500	1,458
	$ 11,135	$ 4,404	$ 6,731

General and administrative expenses were $11.1 million for the three months ended September 30, 2026, compared to $4.4 million for the three months ended September 30, 2025. The increase in general and administrative expenses of $6.7 million was primarily due to an increase of $5.3 million in employee-related expenses, including an increase in stock-based compensation expense of $4.3 million, and an increase of $1.5 million in professional fees and other expenses, including expenses related to being a public company.

Other Income, Net

Interest Income

Interest income was $3.1 million for the three months ended September 30, 2026, compared to $1.5 million for the three months ended September 30, 2025. The increase in interest income of $1.5 million was due to an increase in investments held during the three months ended September 30, 2026 compared to the three months ended September 30, 2025.

Other Income, Net

Other income, net was $0.6 million for the three months ended September 30, 2026, compared to $0.5 million for the three months ended September 30, 2025. The increase of $0.1 million was primarily due to an increase in the amortization of premiums and accretion of discounts to maturity for investments held during the three months ended September 30, 2026.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 151,328	$ 73,726	$ 77,602
General and administrative	32,067	11,980	20,087
Total operating expenses	183,395	85,706	97,689
Loss from operations	(183,395)	(85,706)	(97,689)
Other income, net:			
Interest income	7,915	3,048	4,867
Other income, net	3,004	1,054	1,950
Net loss	$ (172,476)	$ (81,604)	$ (90,872)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Clinical trial expenses	$ 61,121	$ 29,874	$ 31,247
Employee-related expenses	51,100	21,050	30,050
Chemistry, manufacturing and controls expenses	17,876	11,728	6,148
Preclinical program expenses	18,316	7,042	11,274
Other expenses	2,915	4,032	(1,117)
	$ 151,328	$ 73,726	$ 77,602

Research and development expenses were $151.3 million for the nine months ended September 30, 2026, compared to $73.7 million for the nine months ended September 30, 2025. The increase in research and development expenses of $77.6 million was primarily due to ongoing advancement of our product candidates, which included an increase of $31.2 million in clinical trial expenses and an increase of $30.1 million in employee-related expenses, including an increase in stock-based compensation expense of $16.7 million. For the nine months ended September 30, 2025, research and development expenses were reduced due to grant earnings recognized of $2.0 million. For the nine months ended September 30, 2026, no grant earnings were recognized.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Employee-related expenses	$ 19,941	$ 5,866	$ 14,075
Professional fees and other expenses	12,126	6,114	6,012
	$ 32,067	$ 11,980	$ 20,087

General and administrative expenses were $32.1 million for the nine months ended September 30, 2026, compared to $12.0 million for the nine months ended September 30, 2025. The increase in general and administrative expenses of $20.1 million was primarily due to an increase of $14.1 million in employee-related expenses, including an increase in stock-based compensation expense of $11.4 million, and an increase of $6.0 million in professional fees and other expenses, including expenses related to being a public company.

Other Income, Net

Interest Income

Interest income was $7.9 million for the nine months ended September 30, 2026, compared to $3.0 million for the nine months ended September 30, 2025. The increase in interest income of $4.9 million was due to an increase in investments held during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025.

Other Income, Net

Other income, net was $3.0 million for the nine months ended September 30, 2026, compared to $1.1 million for the nine months ended September 30, 2025. The increase of $2.0 million was primarily due to an increase in the amortization of premiums and accretion of discounts to maturity for investments held during the nine months ended September 30, 2026.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant net losses since inception. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future as we advance our current and future product candidates through preclinical and clinical development, seek regulatory approval for such product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, expand our infrastructure, scale up production capabilities and operate as

a public company. As of September 30, 2026, we had cash, cash equivalents and investments of $463.4 million and an accumulated deficit of $533.0 million. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock, and most recently, with net proceeds from our IPO, our Concurrent Private Placement and our 2026 Private Placement.

In October 2025, we closed our IPO, pursuant to which we issued and sold an aggregate of 16,962,500 shares of our common stock at a price of $17.00 per share for net proceeds of $261.6 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with our IPO, we also closed our Concurrent Private Placement, in which we issued and sold 476,707 shares of our common stock at a price of $17.00 per share for net proceeds of $7.5 million, after deducting placement agent fees and private placement expenses.

On August 13, 2026, we entered into a securities purchase agreement with certain institutional investors pursuant to which we agreed to sell and issue, the 2026 Private Placement, (i) 9,197,887 shares of common stock, and (ii) with respect to certain investors, pre-funded warrants to purchase 3,983,168 shares of common stock in lieu of shares of common stock. The purchase price per share of common stock was $11.38 per share and the purchase price for the pre-funded warrants was $11.3799 per share of common stock underlying the pre-funded warrants. We received net proceeds of approximately $140.1 million from the 2026 Private Placement, after deducting placement agent fees and offering expenses of approximately $10.0 million.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Net cash provided by (used in):			
Operating activities	$ (131,725)	$ (91,308)	$ (40,417)
Investing activities	(2,358)	(80,654)	78,296
Financing activities	143,789	197,855	(54,066)
Increase in cash, cash equivalents and restricted cash	$ 9,706	$ 25,893	$ (16,187)

Operating Activities

Our cash flows from operating activities are primarily driven by our use of cash for operating expenses and working capital required to support our business. We have historically generated negative cash flows from operating activities primarily due to expenses incurred for our clinical trials, preclinical studies and research and development initiatives.

During the nine months ended September 30, 2026, net cash used in operating activities was $131.7 million, primarily resulting from our net loss of $172.5 million, which was primarily attributable to our research and development expenses, partially offset by changes in our operating assets and liabilities of $13.1 million and $27.7 million of non-cash items.

During the nine months ended September 30, 2025, net cash used in operating activities was $91.3 million, primarily resulting from our net loss of $81.6 million, which was primarily attributable to our research and development expenses, along with changes in our operating assets and liabilities of $11.1 million, partially offset by $1.4 million of non-cash items.

Investing Activities

Net cash used in investing activities was $2.4 million for the nine months ended September 30, 2026, compared to net cash used in investing activities of $80.7 million for the nine months ended September 30, 2025. The change in cash used in investing activities during the nine months ended September 30, 2026 was driven by the maturities and redemptions of investments.

Financing Activities

Net cash provided by financing activities was $143.8 million for the nine months ended September 30, 2026, compared to net cash provided by financing activities of $197.9 million for the nine months ended September 30, 2025. The decrease in cash provided by financing activities was primarily due to the difference in net proceeds received from the issuance and sale of shares of our Series D redeemable convertible preferred stock during the nine months ended September 30, 2025 compared to the net proceeds received from our 2026 Private Placement during the nine months ended September 30, 2026.

Plan of Operation and Future Funding Requirements

We use our capital resources mainly to fund operating expenses, including research and development expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue clinical trial and preclinical activities. At this time, due to the inherently unpredictable nature of clinical and preclinical development and given the early stage of our product candidates, we cannot reasonably estimate the costs that we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if any. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As of September 30, 2026, we had cash, cash equivalents and investments of $463.4 million. Based on our current operational plans and assumptions, we expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

The timing and amount of our operating expenditures will depend largely on:

- the scope, timing, progress, costs and results of discovery efforts, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the costs of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our platform in identifying additional targets and indications of interest;
- our ability to maintain existing and establish new strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, market access, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of any of our product candidates for which we receive marketing approval;
- the expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- our ability to address any potential supply chain interruptions or delays;
- our ability to mitigate the impact of adverse macroeconomic or geopolitical conditions, including the ongoing conflicts between Ukraine and Russia and in the Middle East, inflation, tariffs and fluctuations in interest rates or other factors, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Our existing cash, cash equivalents and investments will not be sufficient to complete development of any product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until we can generate substantial revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings. We may also consider entering into collaborations, strategic alliances and licensing arrangements or selectively partnering for clinical development and commercialization as well as funding through other sources. The sale of additional equity or convertible debt may result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financial covenants that could restrict our operations or our ability to incur additional indebtedness or pay dividends, among other things. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs or cease operations. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Contractual Obligations and Commitments

Leases

We have a lease for office and laboratory space located in South San Francisco, California. The lease term will be seven years from the lease commencement date and includes an option to extend the lease for an additional five years. The lease has not yet commenced, and accordingly, as of September 30, 2026, no right-of-use asset or lease liability has been recognized and no lease expense has been recorded related to this lease. We expect the lease to commence in May 2027, subject to completion of the landlord's tenant improvements and delivery of the premises. Lease payments will begin one year after the commencement date. Lease payments from October 1, 2026 through the end of the lease term total $13.4 million.

We have a lease for office and laboratory space located in Redwood City, California, with a term that was scheduled to continue until June 2031. We and the lessor had the ability to terminate the lease with 15 months' notice, and in June 2026, we provided this notice to the lessor, changing the end of the term of the lease to September 2027. The lease provides for escalating annualized base rent payments starting at $0.8 million and increasing to $1.0 million in the final year of the lease. Remaining lease payments from October 1, 2026 through the end of the lease term total $1.0 million.

We have a lease for office space located in Burlington, Massachusetts, with a term that extends to May 2029, and with an option to extend the term for an additional five years. Remaining lease payments from October 1, 2026 through the end of the lease term total $0.9 million.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other vendors to assist in the performance of our clinical trials, CMC, research and development and other services and products for operating purposes. These contracts typically do not contain minimum purchase commitments and generally provide for termination on notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation, and may also include termination penalties. As of September 30, 2026, the timing, amount or likelihood of such payments are not known.

Grant and License Agreements

We are party to certain grant agreements with the Michael J. Fox Foundation and license and collaboration agreements with NeuroSolis, Stanford University, Vanderbilt University and other third parties. We may be obligated to make certain future payments under these agreements that are contingent upon future events such as our achievement of specified preclinical, clinical, regulatory and commercial milestones or royalties on net product sales under these agreements. As of September 30, 2026, we were unable to estimate the timing or likelihood of achieving future milestones or generating future product sales under any of these agreements.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements included elsewhere in this Quarterly Report, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make

estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our 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.

A summary of our critical accounting policies is presented in Note 2 to our audited consolidated financial statements as of and for the year ended December 31, 2025 included in our Annual Report on Form 10-K. There were no material changes to our critical accounting policies during the three months ended September 30, 2026.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act, or JOBS Act, provides that, among other things, an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. We may choose to adopt early any new or revised accounting standards whenever such early adoption is permitted for private companies. We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700 million as of the last business day of the second fiscal quarter of such year (and we have been a public company for at least 12 months, have filed one annual report on Form 10-K and are not eligible to use the requirements for smaller reporting companies under the revenue test under Rule 12b-2) or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. 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 million or (ii) our annual revenue is less than $100 million and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2026, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as set forth 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 a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, 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 September 30, 2026, our principal executive officer and principal 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 were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are 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 legal proceedings arising in the ordinary course of our business. We currently are not party to any legal proceedings material to our operations or to which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority. Regardless of outcome, any such proceedings or claims could have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors and there could be no assurances that any favorable outcomes would be obtained.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risk Factor Summary

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in this "Risk Factors" section, including the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of product candidates and the prospects for our future viability.
- We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- If we encounter difficulties enrolling patients in our ongoing or planned clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our product candidates may be associated with serious adverse events, undesirable side effects or other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- Future partnerships may be important to our business. If we are unable to enter into new partnerships, or if these partnerships are not successful, our business could be adversely affected.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel and our inability to do so could adversely affect our business, operations and prospects.
- We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. Furthermore, our reliance on third parties, such as manufacturers,

may subject us to risks relating to manufacturing scale up, which may cause us to undertake substantial obligations, including financial obligations.

- If we are unable to obtain and maintain sufficient intellectual property protection for our current or future product candidates or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be impaired.
- An active trading market for our common stock may not continue to be sustained.
- The trading price of shares of our common stock may be volatile, and purchasers of our common stock could lose all or part of their investment.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of product candidates and the prospects for our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in 2018 and our operations to date have been limited to organizing, staffing and financing our company, and conducting research and development activities, including developing our platform, conducting clinical trials for our product candidates and establishing our intellectual property portfolio. If we are successful in achieving regulatory approval for our product candidates, we will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. Moreover, as an organization, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization or generate revenue. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make 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.

We have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because development efforts entail substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable, have incurred substantial losses in each period since our inception and expect to incur substantial losses for the foreseeable future.

For the nine months ended September 30, 2026 and 2025, our net losses were $172.5 million and $81.6 million, respectively. As of September 30, 2026, we had an accumulated deficit of $533.0 million. Substantially all of our losses have resulted from expenses incurred in connection with the development of our platform, research and development, clinical trials and from general and administrative costs associated with our operations. We expect to incur substantial losses for the foreseeable future, and we expect these losses to increase as we continue the development of our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- conduct additional clinical trials for ML-007C-MA;
- seek regulatory approvals for our product candidates that complete clinical trials or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- oversee, maintain and expand our external manufacturing relationships;
- attract, hire and retain qualified personnel;

- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials; and
- incur additional costs, including legal, accounting and other expenses, associated with operating as a newly public company.

We have no product candidates approved for commercial sale and have not generated any revenue from the sale of products. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, one of our product candidates for either our initial or potential additional indications or any other product candidates we may develop.

Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we or any of our future collaborators may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenue we may generate, the extent of any further losses we may experience and if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenue that is large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the FDA or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any additional delays in completing our clinical trials or the development of any of our product candidates.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue in the future. Our prior losses and expected future losses have had and will continue to have a material adverse effect on our stockholders' equity and working capital and may have a material adverse effect on our business, financial condition, results of operations and prospects. Our failure to become and remain profitable may decrease the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product portfolio or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies and clinical trials of our current and future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products if we receive regulatory approval. As of September 30, 2026, we had cash, cash equivalents and investments of $463.4 million. Based on our current operational plans and assumptions, we expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2028. This estimate is based on assumptions that may prove to be wrong, and our future capital requirements and the period through which our existing resources will support our operations may vary significantly from what we expect. We will require additional capital in order to complete clinical development of any of our current programs, and our spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our programs and product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs and results of discovery efforts, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;

- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our platform in identifying additional targets and indications of interest;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, market access, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- our ability to address any potential supply chain interruptions or delays;
- our ability to mitigate the impact of adverse macroeconomic or geopolitical conditions, including the ongoing conflicts between Ukraine and Russia and in the Middle East, inflation, tariffs and fluctuations in interest rates or other factors, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

We will require substantial additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including fluctuations in interest rates, inflation and concerns of a recession in the United States or other major markets, potential tariffs and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Weakness and volatility in the capital markets and the economy in general could also increase our costs of borrowing. Such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. Any future 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, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could materially and adversely impact our business, financial condition, results of operations and prospects.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our capital needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we may be required to significantly delay, limit, reduce or terminate our

product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Additionally, these circumstances could require that we undertake workforce reductions or restructuring activities in the future. Any of the above events could materially and adversely affect our business, financial condition, results of operations and prospects and cause the price of our common stock to decline.

Risks Related to the Design, Development, Approval and Commercialization of our Product Candidates

If we are unable to successfully identify, develop and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially and adversely affected.

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, depends heavily on the successful identification, development, regulatory approval and eventual commercialization of product candidates, which may never occur. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for or commercialize a marketable product. All of our product candidates will require significant clinical development, regulatory approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

The successful development of our product candidates will depend on several factors, including the following:

- successful and timely completion of preclinical studies and gaining agreement on the design, endpoints and implementation of clinical trials with the FDA or any comparable foreign regulatory authority;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting future clinical trials;
- initiation of and successful patient enrollment in, and completion of, clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's benefit risk assessment for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- effectively competing with other therapies available on the market or in development; and
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline.

Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we experience significant delays or are otherwise unable to successfully commercialize our product candidates, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields may impact the clinical development of and regulatory pathway for our current or future product candidates or may negatively impact the perceptions of value or risk of our product candidates or technologies.

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

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any of our product candidates. We must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Clinical development is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events, or AEs, that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. For example, in June 2026, we announced topline results from IRIS, an exploratory signal-finding Phase 2 study designed to test multiple clinical endpoints based on preclinical findings, which did not meet its primary endpoint.

Additionally, given that ML-007C-MA is a fixed-combination drug product, we will need to demonstrate that each component of the product candidate makes a contribution to the claimed effects (safety and tolerability) and the dosage of each component (amount, frequency, duration) in combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. In addition, if the PAC we have selected has regulatory challenges, it may adversely impact the development of our fixed-combination drug product. It is possible that even if one of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of one of our product candidates that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by one of our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not, in fact, the case. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including inclusion or exclusion criteria, in our clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, financial condition, results of operations and prospects. There is no assurance that the endpoints and trial designs used for the approval of currently approved drugs will be acceptable for future approvals, including for those of our product candidates. For example, in 2024, the FDA published revised draft guidance for drug development in early AD with a recommendation to use consensus diagnostic criteria intended to establish the true biological presence of AD, rather than criteria based on syndromic or other definitions. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from our current or future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates, and therefore materially and adversely impact our business, financial condition, results of operations and prospects.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trials may not be successful.

We may experience delays in initiating or completing our clinical trials or preclinical studies. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, independent institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial, at a prospective or existing trial site;
- we may not reach 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;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, the number of competing clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial or patients may drop out of clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend a clinical trial protocol submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, the supply or quality of product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, in January 2022, our Phase 2 ML-004 clinical trial was placed on a partial clinical hold by the FDA with respect to the enrollment of adolescents pending submission of safety data from the adult cohorts to the FDA. This partial clinical hold was removed by the FDA in October 2024. In addition, our investigational new drug application, or IND, for ML-007C-MA was put on clinical hold by the FDA in May 2024 due

to nonclinical findings associated with a single-agent animal study for ML-007. This hold was lifted in July 2024 after the FDA's review of additional clinical and nonclinical data, and we initiated the Phase 2 trials in the United States for ADP and schizophrenia in May 2025 and June 2025, respectively. We cannot assure you that our existing and future INDs will not be subject to additional clinical holds, whether partial or full. If we are not able to complete successful clinical trials on the schedule we expect, we will not be able to obtain regulatory approval, and will not be able to commercialize our product candidates, on the timelines we expect. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates, which may materially and adversely affect our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our ongoing or planned clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may 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. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or might require us to abandon one or more clinical trials altogether. Our clinical trials may face delays if we are required to restrict enrollment to a more selective group of participants based on age, disease severity or biomarkers, among other factors. For example, in 2024 the FDA published revised draft guidance for drug development in early AD with a recommendation to use consensus diagnostic criteria intended to establish the true biological presence of AD, rather than criteria based on syndromic or other definitions. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process, prevent completion of these trials and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

Obtaining authorization from regulatory authorities for clinical trials in adolescents and pediatric patients may require longer duration of studies than we currently anticipate, which could delay our development programs or preclude us from pursuing approval in the populations for which we are seeking approval.

Pediatric drug development, including with respect to ML-004 for the treatment of adolescents, may require additional trials to determine safe dosing and long-term safety. These additional trials may require investment of significant additional resources beyond those required for regulatory approval of the drugs in adults. We cannot guarantee that we will receive regulatory approval to commercialize our product candidates in the pediatric populations or the adult population.

We conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We conduct certain clinical trials for our product candidates outside of the United States. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice, or GCP, regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well designed and well conducted in accordance with GCP regulations and the FDA is able to validate the data from the study through an onsite inspection, if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time consuming and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenue or become profitable.

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the occurrence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;

- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of our sales, marketing and distribution support, including having sufficient staffing and financial resources;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would materially and adversely affect our business, financial condition, results of operations and prospects.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, such as the topline results from our Phase 2 trial evaluating ML-007C-MA for the treatment of schizophrenia and the topline results from our Phase 2 trial evaluating ML-004 in adults and adolescents with ASD. These topline results are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Our product candidates may be associated with serious adverse events, undesirable side effects or other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approvals by the FDA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. If any serious adverse events occur during clinical development, clinical trials could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, or deny approval of, our product candidates. If we are

required to delay, suspend or terminate any clinical trial or our development efforts, the commercial prospects of our product candidates may be harmed, and our potential to generate product revenues from them may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, limit or withdraw approvals of such product or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ML-007C-MA, ML-004 or any of our other product candidates, if approved, and could seriously harm our business.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of our current product candidates are our initial focus, as part of our longer-term growth strategy, we plan to develop other product candidates. In addition to the product candidates in our clinical-stage pipeline, we have additional assets that are in earlier stages of development. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates and also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our platform may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;

- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We may expend our limited resources to pursue a particular product candidate or indication and forego the opportunity to capitalize on product candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed in terms of their potential for regulatory approval, unmet need and potential commercial success. As a result, we may forego, delay or explore alternative development strategies, including partnership, spin-off or divestment, of our other product candidates or forego other indications, all of which may prove to have greater commercial potential than the product candidates and indications we pursue.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate, including through entering into collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We have concentrated our research and development efforts on the treatment of disorders of the central nervous system, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing disorders of the CNS. Efforts by biotechnology and pharmaceutical companies in this field have faced certain challenges in drug development historically. For example, we are currently developing ML-007C-MA for the treatment of schizophrenia and ADP, and clinical trials focused on neuropsychiatric diseases such as schizophrenia or ADP rely on subjective patient-reported outcomes as key endpoints. This makes these trials more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. There can be no guarantee that we will successfully overcome these challenges with our product candidates or that we will not encounter other challenges in the development of our product candidates.

We may in the future seek to engage in strategic transactions to acquire or in-license additional products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize an expanded pipeline of product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, product candidates or technologies that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any such strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures, experience significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities; disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies; incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;

higher-than-expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges; increased amortization expenses; difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business; impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and could have a negative impact on the competitiveness of any product candidate that reaches market.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop, and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, is subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction, and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude their obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenue will be materially impaired.

We may face uncertainty related to pricing, coverage and reimbursement for our product candidates.

Successful sales of our product candidates in the U.S. market, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs like Medicaid and Medicare, or private health insurance (including managed care plans). These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. Third-party payors are increasingly reducing coverage for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Patient copays can be significant and may vary among products within a class depending upon the formulary status of an agent with a particular payor. Inconsistencies in formulary status across state Medicaid plans and commercial payors may result in coverage gaps in some geographical areas.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party coverage for our product candidates, if approved, or a decision by a third-party payor to not cover our product candidates could have a material adverse effect on our sales, results of operations, and financial condition. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates if approved will be harmed.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a product candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or significant taxes or fees.

The market for our current or future product candidates may be smaller than we expect.

Our estimates of the potential market opportunity for ML-007C-MA for the treatment of patients with schizophrenia and ADP, ML-004 for ASD and any other product candidates we may develop include several key assumptions based on our industry knowledge, industry publications and third-party research reports. There can be no assurance that any of these assumptions are, or will remain, accurate. If the actual markets for ML-007C-MA or ML-004 for these or other indications, or for any other product candidate we may develop, are smaller than we expect, our revenue, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our product candidates, approach, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with approved treatment options, off-label therapies and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites, patient registration for clinical trials and 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.

Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We are developing ML-007C-MA for the treatment of schizophrenia, ADP and other potential indications. We may face competition from typical and atypical antipsychotic treatments that work primarily by inhibiting dopamine and serotonin receptors. In addition, we are aware of several product candidates in development that are designed to modulate muscarinic receptors, such as Cobenfy (also known as KarXT), which is marketed for the treatment of schizophrenia and being developed for additional indications by Bristol-Myers Squibb Company; emraclidine, which is being developed by AbbVie Inc.; direclidine, NBI-'570 and NBI-'567, which are being developed by Neurocrine Biosciences, Inc.; and NMRA-861 and NMRA-898, which are being developed by Neumora Therapeutics, Inc. and Syremis Therapeutics Ltd.

We may also face competition from other companies developing product candidates to address schizophrenia, ADP and other relevant indications that are designed to modulate other non-muscarinic receptors, including ACP-204, which is being developed by

Acadia Pharmaceuticals, Inc. We may also face competition from other companies developing product candidates to address agitation or other behavioral symptoms associated with Alzheimer's disease.

We are developing ML-004 for the treatment of ASD. There are currently no FDA-approved pharmaceutical treatments for social communication deficits in ASD. In the treatment of the irritability symptoms associated with ASD, we may face competition from ABILIFY, marketed by Otsuka Pharmaceutical Co., Ltd., and RISPERDAL, marketed by Johnson & Johnson, as well as from generic forms of those drugs that are being marketed and sold.

Even if we obtain FDA approval of any of our product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our 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 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 our ability to realize the full market potential of any product we develop will be unrealized.

If we obtain approval to commercialize any products outside of the United States, we could experience a variety of risks associated with international operations that could adversely affect our business.

If any of our current or future product candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and companion diagnostic approvals and rules governing drug and companion diagnostic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or impacts related to tariffs, fluctuating interest rates or other factors, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we will need to comply. If we are unable to successfully manage the challenges

of international expansion and operations, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop, which could adversely affect our business, financial condition, results of operations and prospects.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims could include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims also could be asserted under state consumer protection acts. Product liability claims could delay or prevent completion of our development programs. If we cannot successfully defend ourselves against any claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- inability to bring a product candidate to market;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by U.S. and foreign regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and resources from our business operations;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- reduced resources of our management to pursue our business strategy;
- the inability to commercialize any products that we may develop; and
- decline in our stock price.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of ML-007C-MA, ML-004 or our future product candidates. Insurance coverage is increasingly expensive. Our insurance policies also may have various deductibles and exclusions, and we may be subject to a product liability claim for which we have no coverage. We may need to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, enforcing such indemnification provisions may cause diversion of management's time and our resources and such indemnification may not be available or adequate should any claim arise. A successful product liability claim or series of claims brought against us could decrease our cash and cash equivalents and materially and adversely affect our business, results of operations, financial condition and prospects.

Risks Related to Government Regulation

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

Any product candidate for which we obtain marketing approval will be subject to ongoing regulatory requirements for, among other things, manufacturing processes, submission of post-approval clinical data and safety information, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, promotional activities and product tracking

and tracing. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current good manufacturing practice, or cGMP, regulations relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP regulations for any clinical trials that we conduct post-approval.

In addition, later discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies, and the policies of foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

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. For example, executive orders or other actions could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. If such executive actions were to impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business could be negatively impacted. In addition, 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 decisions 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. 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 which would materially and adversely affect our business, financial condition, results of operations and prospects.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our

ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances.

Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil penalties or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could materially and adversely impact our business, financial condition, results of operations and prospects.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the agency's ability to perform routine functions. Average review times at the FDA and other government agencies 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 or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, 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. In addition, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If any future prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and in either case may not be successful.

We are developing a proprietary product candidate for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section

505(b)(2) regulatory pathway, we cannot assure you that our product candidate will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidate is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. 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 healthcare.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted in the United States in 2010 and substantially changed the way healthcare is financed by both the government and private insurers. Since the ACA's passage, legislative changes to the ACA have been proposed and adopted. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA's enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA is also expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Additionally, under the sequestration required by the Budget Control Act of 2011, beginning April 1, 2013, Medicare payments to providers were reduced, which will remain in effect through 2032 unless additional Congressional action is taken.

The current Presidential administration is pursuing policies to reduce regulations and expenditures across the federal government, including at the U.S. Department of Health and Human Services, or HHS, the FDA, the Centers for Medicare & Medicaid Services, or CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, patients in the United States and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than that paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other actions and proposals include, for example: (1) directing agencies to reduce workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing most-favored-nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission’s Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price

transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process and make changes to modify the Medicare Drug Price Negotiation Program.

At the state level, legislatures and state agencies have increasingly passed legislation and implemented regulations that are designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, that are designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely impact our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Any of these actions could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could materially and adversely affect our business, financial condition, results of operations and prospects.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product.

If we or our third-party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Although we do not currently manufacture our drug products or product candidates on site, our research and development activities do involve the use of biological and hazardous materials and produce hazardous waste products in small quantities. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, which includes coverage for biological hazardous waste and medical hazardous waste or radioactive contamination, this insurance may not provide adequate coverage against potential liabilities.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers subject us to broadly applicable foreign, federal and state 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 any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease or order or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; some state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products.

Efforts to ensure that our current and future business arrangements and those with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the

narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time consuming and may require significant financial and 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and data we collect about trial participants in connection with clinical trials (collectively, sensitive data).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws).

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights include the right to access, correct or delete certain personal data, and to opt out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents.

Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's General Data Protection Regulation, or UK GDPR, Australia's Privacy Act, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, Law No. 13,709/2018), South Korea's Personal Information Protection Act (PIPA), Chile's new Personal Data Protection Law (Law No. 21.719), Argentina's Personal Data Protection Law (PDPL), Mexico's Federal Law on the Protection of Personal Data held by Private Parties, and China's Personal Information Protection Law impose strict requirements for processing personal data. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may apply to our operations.

For example, under the General Data Protection Regulation, or GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, and 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws they generally believe are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the United Kingdom to the United States in compliance with law, such as the EEA's standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum and the European Union-U.S. Data Privacy Framework and the United Kingdom extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom or other jurisdictions to the United States or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and the United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions occurring on or after the effective date of the rule involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business and management activities, such as licensing and partnership engagements, vendor engagements, employment of or access to data by certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. Although the U.S. Department of Justice has issued compliance guidance and responded to frequently asked questions, there is currently no enforcement or case law to provide additional guidance on how the rule will be interpreted by the U.S. Department of Justice, and there is a risk that our interpretation of its applicability, scope and requirements could be incorrect, incomplete, or misapplied. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer or provide access to data in connection with certain transactions or agreements.

We use or plan to use artificial intelligence, or AI, including generative AI, and machine learning, or ML, technologies in the development of our current or future product candidates, which we refer to collectively as "AI/ML" technologies. For example, we use an internally developed algorithm for drug discovery purposes and to identify drug targets. The development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering laws governing the development and use of AI/ML, such as the EU's AI Act and Colorado's AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage. Our employees and personnel also use AI and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are and may in the future become contractually subject to industry standards adopted by industry groups. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials and other statements regarding data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

The requirements of such obligations, their application, and interpretation (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail or are perceived to have failed to address or comply with applicable data privacy and security obligations, we could face significant consequences, including government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including our inability to process personal data or to operate in certain jurisdictions; our limited ability to develop or commercialize our products; our expenditure of time and resources to defend any claim or inquiry; adverse publicity we may encounter; or by requiring substantial changes that may be required to our business model or operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

A Fast Track designation from 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 does not increase the likelihood that our product candidates will receive regulatory approval.

The FDA has granted Fast Track designation to ML-007C-MA for the treatment of hallucinations and delusions associated with ADP. We intend to seek such designation for some or all of our additional product candidates. Drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and,

once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that ML-007C-MA or any other product candidate that may be granted Fast Track designation will receive regulatory approval in the United States. Many product candidates that have received Fast Track designation have ultimately failed to obtain regulatory approval.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with Good Laboratory Practice, or GLP, regulations as applicable, and GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLP and GCP regulations through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLP and GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, we may be required to add more clinical trial sites or enroll additional participants and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. For example, certain companies developing drugs for the treatment of Alzheimer's disease and related conditions have recently reported enrollment irregularities and potential misconduct by certain of their clinical sites, including falsification of data and enrolling participants that may not have met inclusion and exclusion criteria. We cannot assure you that upon inspection by a given regulatory authority such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. Further, these laboratories, investigators and CROs are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional laboratories or CROs or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. Furthermore, our reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale up, which may cause us to undertake substantial obligations, including financial obligations.

We do not currently have the infrastructure or capability internally to manufacture all our product candidates for use in the conduct of our preclinical studies and clinical trials or, if our products are approved, for commercial supply. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. For example, we currently rely on a limited number of single-source suppliers for manufacturing components of ML-007C-MA. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the manufacture of our product candidates in accordance with relevant regulations, such as cGMP regulations, which require, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approvals for or commercialize our products and product candidates. 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 revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our third-party manufacturers and other vendors may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, war, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or ongoing and planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, and with the appropriate volumes, who could meet our timelines at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could

significantly delay our preclinical studies, our clinical trials and the commercialization of our products, if approved, which could materially and adversely affect our business, financial condition, results of operations and prospects. In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA and comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP regulations or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on CMOs, as any disruption, such as a fire, natural hazards, vandalism or an outbreak of contagious disease affecting the CMO or any supplier of the CMO could significantly interrupt our manufacturing capability. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience significant manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

In addition, we currently rely on foreign CMOs for manufacturing and development activities and will likely continue to rely on foreign CMOs in the future. Foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the BIOSECURE Act, which was recently enacted as part of the fiscal year 2026 National Defense Authorization Act and signed by the President on December 18, 2025, prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern” in the performance of that contract, which may impact one of our contract development and manufacturing organizations, or CDMOs. It also prohibits loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a “biotechnology company of concern” in the performance of the government grant or loan. This legislation could have the downstream effect of restricting the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act, as well as supply chain disruptions or delays. In addition to the BIOSECURE Act, any additional executive action, legislative action or potential sanctions with China could materially impact our work. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

Furthermore, as we continue to grow and advance our product candidates through clinical trials, we will need to scale our operations accordingly. For example, as we conduct clinical trials of our product candidates, we need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Future partnerships may be important to our business. If we are unable to enter into new partnerships, or if these partnerships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into future partnerships with other companies to provide us with additional product candidates and funding for our programs or to help commercialize our products, if approved. If we are unable to successfully develop and commercialize our own products and are required to pursue partnerships, we may fail to enter into or maintain such partnerships on reasonable terms or at all, our ability to develop our research programs and product candidates could be delayed and our costs of development and commercialization could increase. In addition, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

We may not be able to negotiate partnerships on a timely basis, on acceptable terms, or at all. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the partner's resources and expertise, the terms and conditions of the proposed partnership and the proposed partner's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

Risks Related to Employee Matters and Our Operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel, and our inability to do so could adversely affect our business, operations and prospects.

We are highly dependent on the management, clinical, research and development, manufacturing, financial and business development expertise of our executive officers, particularly Christopher A. Kroeger, M.D., our Chief Executive Officer and Founder, and Erin Foff, M.D., Ph.D., our Chief Medical Officer. Each of our executive officers may terminate their employment with us at any time. We do not currently maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key personnel, including any of our scientific founders, could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. 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 successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our 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, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple CNS indications may negatively affect our ability to adequately develop the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may be improperly classified or may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We endeavor to properly classify our employees as exempt or non-exempt with respect to wage and hour laws, including for purposes of minimum wage, overtime and applicable meal and rest periods, and we monitor and evaluate such classifications. Although there are no current, pending or threatened claims or investigations against us asserting that any employees have been incorrectly classified as exempt, the possibility nevertheless exists that certain job roles could be deemed to have been incorrectly classified as exempt. In addition, we endeavor to classify our workforce properly, and we monitor and evaluate such classifications.

Although there are no current, pending or threatened claims or investigations against us asserting that any independent contractors have been incorrectly classified, the possibility nevertheless exists that certain contractors could be deemed to be employees.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

If our information technology systems or those of third parties with whom we work or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, and, as a result, we and third parties with whom we work face a variety of evolving threats that can cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems, and those of third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our services.

We and third parties with whom we work are subject to a variety of evolving threats, including social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct, human or technological error, ransomware attacks, supply chain attacks, software bugs or other vulnerabilities in commercial software that is integrated into our or our service providers' information technology systems, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI (including tools that circumvent security controls, evade detection and remove forensic evidence), telecommunications failures, earthquakes, fires, floods, and other similar threats. Such threats are expected to accelerate on a global basis in frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations or our ability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of

one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply chain attacks, and other threats to our business operations. We rely on third parties and their technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, CROs, cybersecurity service providers, employee email and other functions. We also rely on third parties to provide other products, services, parts or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or their supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). However, we may not detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats could cause a security incident or other adverse impact to the availability, integrity or confidentiality of our sensitive data or our information technology systems, or those of third parties with whom we work, including unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to such sensitive data and systems. A security incident or other adverse impact could disrupt our ability (and that of third parties with whom we work) to provide our services.

We may need to expend additional resources or may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related action can be costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Our use of AI/ML presents certain information security risks. For example, any sensitive data that we input into an AI/ML platform could be leaked or disclosed to others, including if sensitive data is used to train third-party AI/ML. Where an AI/ML model ingests sensitive data and makes connections using such data, those technologies may reveal other sensitive data generated by the model. AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination").

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive data (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, diversion of our capital resources, diversion of management attention, interruptions in our operations (including availability of data), financial loss, and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Any or all of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

Some of our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our current or future product candidates or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be impaired.

Our success depends in large part on our ability to obtain, maintain, defend and enforce our intellectual property, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad and in-licensing intellectual property related to our existing product candidates, our various proprietary technologies and any other product candidates or technologies that we may identify.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the rights to patents licensed from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of significant litigation. The standards that the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending application or later invalidate or narrow the scope of an issued patent. For example, 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, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In some instances, we submit patent applications directly with the USPTO as provisional patent applications. However, U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of the provisional application filing date. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Any pending and future patent applications that we own or in-license may not result in patents being issued that protect our product candidates or technology, in whole or in part, or that effectively prevent others from commercializing competitive product

candidates. 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 patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative product candidates in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours or limit the duration of the patent protection of our product candidates. 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 commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. Certain intellectual property related to the ML-007C-MA product candidate that is expected to expire between 2031 and 2032 was developed using U.S. governmental funding. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. For example, the United States federal government retains such rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. Any exercise by the government of such rights or by any third party of its reserved rights could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. In addition, intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Moreover, 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, in European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws, which could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign

government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be materially and adversely affected.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability were met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to a patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-inventor-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This new regime will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications filed after March 2013 are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. For example, 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. For instance, in *Amgen Inc. v. Sanofi*, the U.S. Supreme Court held that claims with functional language may pose high hurdles in fulfilling the enablement requirement. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. For example, recent decisions, including by the U.S. Court of Appeals for the Federal Circuit, raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

Further, the new European unitary patent system took effect on June 1, 2023, under which all European patents, including those granted before the introduction of the system, now by default fall automatically under the jurisdiction of the Unitary Patent Court, or UPC, unless otherwise opted out. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC during the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. We cannot predict with certainty the long-term effects of any potential changes.

Patent terms may be inadequate to protect the competitive position of our product candidates 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 or international patent application 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. 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 commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Amendments and in foreign countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments allow a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, such as the Supplementary Protection Certificates in Europe. In particular, a maximum of five-and-a-half years of supplementary protection can be achieved in Europe for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection.

Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, any failure by us to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, apply prior to expiration of relevant patents or to otherwise satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent or a manufacturer of generic drugs may challenge the listing. If or when one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any Abbreviated New Drug Application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 our competitive advantage. For example:

- we or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we license or may own in the future;
- we or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop, manufacture and commercialize technologies or products that are similar to, or are alternatives or duplicates of any of our technologies or products without infringing, misappropriating or otherwise violating our intellectual property rights;

- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors 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, manufacture and commercialize competitive products or product candidates for sale in our major commercial markets;
- 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 for some of our proprietary technology to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of our owned and licensed patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. However, we cannot guarantee that any current or future licensors have or will have similar systems and procedures in place to pay such fees. In addition, the USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled, 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 those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by any licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain

names, copyrights or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

Moreover, any name we have proposed to use with any of our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, and our issued patents covering our product candidates could be found invalid or unenforceable if challenged in courts or patent offices.

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. If we were to initiate legal proceedings against a third party to enforce a patent covering one or more of our product candidates, the defendant could allege that we infringe their patents, assert counterclaims that the patent covering our product candidate is invalid and/or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

Third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell any product candidates that we may develop without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. The biopharmaceutical industry has produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to issued patents, and a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. In addition, many companies in the biopharmaceutical industry have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biopharmaceutical industry expands and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our existing product candidates and any other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

There may be other third-party patents or patent applications with claims to composition of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our existing or future product candidates. Further, we may not be aware of patents that have already been issued and that a third party might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were determined to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents or until such patents expire.

Similarly, if any third-party patents were found to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we could because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we

can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

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

Our agreements with employees and contractors and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us are our exclusive property. Although our policy is to have all such individuals complete these agreements assigning such intellectual property to us, we may not obtain these agreements in all circumstances, the assignment of intellectual property rights may not be self-executing and individuals with whom we have entered into these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection.

We or our current or future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may 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.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets and other confidential proprietary technology or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and we may need to share our trade secrets or proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties, foreign actors and those affiliated with or controlled by state actors. Over time, trade secrets may also be disseminated within the industry through independent

development, the publication of journal articles and the movement of personnel from company to company or academic institutions to industry scientific positions. Although our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets and proprietary information, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of such information may be greatly reduced and our competitive position, business, financial condition, results of operations and prospects would be materially and adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets or other confidential information of their current or former employers or other third parties.

As is common in the biopharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or other third parties. We may also become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. We may also lose valuable intellectual property rights or personnel, which could adversely impact our business. 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. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We may obtain rights to develop and commercialize product candidates that are subject in part to the terms and conditions of licenses granted to us by others. The terms of these licenses may be inadequate to protect our competitive position on product candidates. Further, if we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, we could lose such rights that are important to our business.

We may in the future seek licenses from others to develop and commercialize product candidates or technologies. The licenses we may enter into may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

We may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, our licensors may require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected, and we may be unable to prevent competitors from making, using and selling competing products.

Our rights to use any intellectual property that we may license in the future will be subject to the continuation of and our compliance with the terms of such a license agreement. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any future 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.

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

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Risks Related to Ownership of our Common Stock and our Status as a Public Company

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

An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, you may be unable to resell your shares of our common stock at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market also may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The trading price of shares of our common stock may be volatile, and purchasers of our common stock could lose all or part of their investment.

The trading price of our common stock could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. In addition to the factors described in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, the market price for our common stock may be influenced by many factors, including:

- the initiation, enrollment or results of our current or future clinical trials we may conduct or changes in the development status of our product candidates;
- any delay in our regulatory filings for our current or future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;

- the reporting of unfavorable clinical or preclinical results;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of our current or future product candidates;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- general conditions or trends in the biotechnology and other industries;
- the overall performance of the equity markets generally, including the stock market performance and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- investors' general perception of our company and our business;
- our failure to meet the third-party estimates and projections of the investment community or those that we may otherwise provide to the public;
- changes in financial estimates published by us or by any equity research analysts who might cover our stock;
- the trading volume of our common stock;
- announcements by us or our competitors of entry into significant acquisitions, strategic partnerships or divestitures;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- introduction of new products or services offered by us or our competitors;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- our ability to effectively manage our growth;
- recruitment or departure of key personnel;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation or employee or independent contractor litigation;
- significant changes in the structure of healthcare payment systems, including with respect to coverage and adequate reimbursement for any approved drug; and
- other events or factors, many of which are beyond our control.

In addition, in the past, securities class action litigation often has been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and prospects.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may materially and adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We could be subject to securities class action litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq-listed and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs (including the cost to defend against and any potential adverse outcome resulting from any such proceeding), damage to our reputation and a diversion of management's attention and resources from other business concerns, which could harm our business, financial condition, results of operations and prospects.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, including Catalyst4, Inc., in the aggregate, hold common stock representing a majority of our outstanding voting common stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. Additionally, the concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the research, development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders therefore will be limited to the appreciation in the price of our common stock.

A significant portion of our total outstanding shares may be sold into the market. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

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 intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

Moreover, holders of an aggregate of approximately 18.4 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered for resale up to 13,181,055 shares of common stock (including shares of common stock issuable upon exercise of pre-funded warrants) that we sold in our 2026 Private Placement.

We have also registered or will register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options on a registration statement on Form S-8 and will continue to register any additional shares that become available under such plans due to any annual, automatic increases under the terms of those plans. These shares can be freely sold in the public market upon issuance, 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.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- an exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements to hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the PCAOB regarding the communication of critical audit matters in the auditor's report on financial statements.

We cannot predict if investors will find our common stock less attractive because we will 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. We plan to take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30th (and we have been a public company for at least 12 months, have filed one annual report on Form 10-K and are not eligible to use the requirements for smaller reporting companies under the revenue test under Rule 12b-2 under the Exchange Act) or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in our periodic reports may be different than the information investors may receive from other public companies in which they hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We also are a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We have broad discretion in the use of our cash, cash equivalents and investments and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion over the use of our cash, cash equivalents and investments, and you will not have the opportunity to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that determine our use of our existing cash, cash equivalents and investments, our ultimate use of proceeds may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and investments in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. We expect to use our existing cash, cash equivalents and investments to advance the clinical development of our current programs and for working capital and other general corporate purposes. In addition, we may use a portion of our existing cash, cash equivalents and investments to pursue our strategy to in-license or develop additional product candidates. We may also invest in short- and long-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest our existing cash, cash equivalents and investments in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and 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 the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our restated certificate or our amended and restated bylaws;
- any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions 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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. 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 our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that directors are elected at the annual stockholder meeting;
- allow the authorized number of our directors to be changed from time to time by our stockholders or our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish requirements for stockholder proposals that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and allow actions by our stockholders by written consent, with certain requirements;
- limit who may call stockholder meetings; and

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of 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 of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that holders of our common stock would receive a premium for their shares of our common stock in an acquisition.

General Risks

We will incur increased costs and demands upon management as a result of being a newly public company.

As a newly public company listed in the United States, we will incur significant additional legal, accounting and other expenses that we did not incur as a private company. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products, if approved. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If we are unable to design and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second Annual Report on Form 10-K.

However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. When we lose our status as an "emerging growth company" and/or reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to

upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Implementing any appropriate changes to our internal control over financial reporting may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in establishing and maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and materially and adversely affect our business, financial condition, results of operations and prospects.

There may be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting or to implement or maintain other effective control systems required of public companies could also restrict our future access to the capital markets.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we had federal and state net operating loss, or NOL, carryforwards of $96.6 million and $13.1 million, respectively. Such federal NOL carryforwards may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such year, if any. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. The state NOL carryforwards begin to expire in 2039. In addition, as of December 31, 2025, we had federal research and development tax credits, or R&D credits, of $13.3 million available to offset our future taxable income, if any, which will expire at various dates beginning in 2039.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and other tax attributes to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, including as a result of our IPO and the Concurrent Private Placement, the 2026 Private Placement or other shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs and our ability to use our NOL carryforwards or R&D credits is materially limited, it would harm our future results of operations by effectively increasing our future tax obligations.

Changes in tax laws or regulations may have a material adverse effect on our cash flow, business, financial condition, results of operations or prospects.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the OBBBA (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to this and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business.

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

Our results of operations could be adversely affected by general conditions in the global economy. Unfavorable conditions in the economy both in the United States and abroad, including conditions resulting from changes in gross domestic product growth in the United States or abroad, financial and credit market fluctuations, inflation, fluctuating interest rates, potential tariffs and other

concerns regarding international trade relations, political turmoil, natural catastrophes, outbreaks of contagious diseases, warfare and terrorist attacks on the United States, Europe, the Asia Pacific region or elsewhere, such as the conflict in the Middle East, could cause a decrease in business investments, disrupt the timing and cadence of key industry events, and negatively affect the growth of our business and our results of operations. For example, the COVID-19 pandemic adversely affected workforces, economies and financial markets globally, leading to a reduction in the ability of, or the inability of, partners, suppliers, vendors or other parties to meet their contractual obligations, and for a period of time, a reduction in customer spending on technology, and such conditions may reoccur in the future. The war in Ukraine and the related political and economic responses imposed on Russia, such as sanctions, may also exacerbate these issues and trends especially in Europe. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business, financial condition, results of operations and prospects.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds from Public Offering of Common Stock

On October 26, 2025, our Registration Statement on Form S-1, as amended (File No. 333-290400), for our IPO became effective, pursuant to which we sold an aggregate of 16,962,500 shares of our common stock for net proceeds of $261.6 million. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus filed pursuant to Rule 424(b)(3) under the Securities Act with the SEC on October 27, 2025.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

None of our directors or executive officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule-10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K, during the fiscal quarter ended September 30, 2026.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on October 29, 2025)
3.2	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on October 29, 2025)
4.1^	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated July 18, 2025 (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
4.2	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on August 13, 2026)
10.1	Form of Securities Purchase Agreement, dated August 13, 2026, by and among the Registrant and the purchasers party thereto (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on August 13, 2026)
10.2	Form of Registration Rights Agreement, dated August 13, 2026, by and among the Registrant and the purchasers party thereto (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on August 13, 2026)
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 and 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 With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
† This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
^ Certain schedules and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MapLight Therapeutics, Inc.

Date: November 16, 2026

By: /s/ Christopher A. Kroeger
Christopher A. Kroeger, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 16, 2026

By: /s/ Jonathan Gillis
Jonathan Gillis
Interim Chief Financial Officer and Chief Administrative and Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher A. Kroeger, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2026 of MapLight Therapeutics, Inc. (the "registrant");
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)) 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) 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
    (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2026

/s/ Christopher A. Kroeger
Christopher A. Kroeger, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Gillis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2026 of MapLight Therapeutics, Inc. (the "registrant");
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)) 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) 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
    (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2026

/s/ Jonathan Gillis
Jonathan Gillis
Interim Chief Financial Officer and Chief Administrative and Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Christopher A. Kroeger, M.D., Chief Executive Officer of MapLight Therapeutics, Inc. (the "Company") and Jonathan Gillis, Interim Chief Financial Officer and Chief Administrative and Accounting Officer of the Company, each hereby certifies that:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 16th day of November, 2026.

/s/ Christopher A. Kroeger	/s/ Jonathan Gillis
Christopher A. Kroeger, M.D. Chief Executive Officer (Principal Executive Officer)	Jonathan Gillis Interim Chief Financial Officer and Chief Administrative and Accounting Officer (Principal Financial and Accounting Officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.