UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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: 001-42490

MAZE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-2635018**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

171 Oyster Point Blvd., Suite 300

South San Francisco, California 94080

(Address of principal executive offices, including zip code)

(650) 850-5070

(Registrant's telephone number, including area code)

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

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $0.001 per share	MAZE	The Nasdaq Stock Market LLC

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, a 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 Act). YES ☐ NO ☒

As of August 5, 2026, the registrant had 55,549,168 shares of common stock outstanding.

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Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and the Private Securities Litigation Reform Act of 1995. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our intent, belief, or current expectations, primarily with respect to our business and related industry developments. In some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our intent, belief, or current expectations, primarily with respect to our business and related industry developments. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the timing of our preclinical studies and clinical trials for our therapeutic candidates, including statements regarding the anticipated timing of initiation and completion of studies or trials, the period during which the results of the trials will become available and our development plans;
- the characteristics, safety, tolerability and efficacy of MZE829, MZE782 or any other therapeutic candidates we may develop;
- our ability to develop, obtain and maintain regulatory approval for our therapeutic candidates or any other therapeutic candidates we may develop, including the timing of and costs involved;
- estimates of our addressable market and market growth, including our estimates regarding the patient populations and market opportunities for our therapeutic candidates;
- our expectations regarding demand for, and market acceptance of, our therapeutic candidates in any of the indications in which we plan to develop them, and any other therapeutic candidates we may develop;
- our ability to use our Compass platform to identify new therapeutic targets and advance such targets into clinical development and validate such targets across multiple indications;
- our ability to maintain and expand access to human genetics data;
- our ability to compete effectively with existing competitors and new market entrants;
- the potential effects of extensive government regulations in the United States and foreign countries relating to our industry;
- our ability to obtain, maintain, protect and enforce intellectual property and proprietary rights;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, including our ability to comply with our financial obligations pursuant to the terms of such agreements;
- the timing and likelihood of the achievement of milestones pursuant to our existing collaboration and licensing agreements;
- our reliance on and performance of third parties, including our clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, suppliers and manufacturers;
- our ability to expand our pipeline of therapeutic candidates;
- our ability to attract and retain key management and technical personnel;

- general economic, industry and market conditions, including fluctuating interest, inflation and tariff rates, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, uncertainty with respect to healthcare policies and regulation, instability in the global banking system, volatile market conditions, supply chain delays, and the ongoing labor shortage;
- the impact of natural disasters, terrorist activity, pandemics, regional conflicts around the world and the global responses thereto and other events beyond our control on any of the above or any other aspect of our business operations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act; and
- our expectations regarding expenses, future revenue, capital requirements, and our needs for additional financing.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events or information as of the date on which the statements are made in this Quarterly Report on Form 10-Q. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed with the Securities and Exchange Commission, or SEC, as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Summary of Risk Factors

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this summary to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, are described under the heading "Risk Factors" in this Quarterly Report on Form 10-Q, and this summary is qualified in its entirety by that discussion. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. You should consider carefully the risks and uncertainties described below and under the heading "Risk Factors" in this Quarterly Report on Form 10-Q.

Some of the principal risks we are exposed to include:

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. Since our inception, we have incurred significant operating losses and have not generated any product revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.
- We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.
- We are early in our development efforts and highly dependent on the success of our lead programs. If we are unable to commercialize our therapeutic candidates or experience significant delays in doing so, our business will be materially harmed.
- Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our therapeutic candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.
- We may not be successful in applying our Compass platform to identify targets with therapeutic potential or to discover and develop safe, effective or commercially viable therapeutic candidates.
- Certain of the diseases we, or which our partners, seek to treat have low prevalence and/or have available therapies, and it may be difficult for us or our partners to identify patients with these diseases or face competition in the recruitment of these limited groups of patients, which may lead to difficulties in enrolling clinical trials.
- Our Compass platform relies on access to high quality data repositories with paired genetic and clinical data and loss of such access, or the inability to use such data, could have a material adverse effect on our business, financial condition, results of operations and prospects.
- We have entered, and may in the future enter, into strategic collaborations, transactions and licensing partnerships for research, development or commercialization of our programs, including our first therapeutic candidate MZE001, and we may not be able to realize the full value of these partnerships or our partnered programs.
- We face significant competition in an environment of rapid technological change and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies or technologies that are more advanced or effective than ours, which may harm our business and financial condition, and our ability to successfully market or commercialize our therapeutic candidates.
- Our success depends in part on our and our partners' ability to obtain, maintain, enforce and protect our intellectual property and proprietary rights. It is difficult and costly to protect our intellectual property rights and technologies, and we may not be able to ensure their protection. If we are unable to adequately protect our technologies or obtain and maintain patent protection for our technologies and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.
- If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time-consuming and could prevent or delay us from developing or commercializing our therapeutic candidates.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Maze Therapeutics, Inc.
Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 202,643	$ 189,247
Marketable securities, current	208,444	152,670
Prepaid expenses and other current assets	9,336	7,800
Total current assets	420,423	349,717
Property and equipment, net	4,391	5,044
Restricted cash	1,088	1,088
Marketable securities, non-current	83,821	18,114
Operating lease right-of-use asset	18,442	20,116
Other assets	3,460	3,048
Total assets	$ 531,625	$ 397,127
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,212	$ 1,794
Accrued expenses and other current liabilities	15,866	15,967
Operating lease liabilities, current	4,883	4,795
Total current liabilities	22,961	22,556
Operating lease liabilities, net of current portion	16,580	18,511
Term loan, non-current	38,960	—
Other liabilities, non-current	—	1,094
Total liabilities	78,501	42,161
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of June 30, 2026 and December 31, 2025; no shares issued and outstanding as of June 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value; 500,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 55,504,574 and 49,335,551 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; 10,372 shares subject to repurchase as of June 30, 2026 and December 31, 2025	56	49
Additional paid-in-capital	1,011,985	844,354
Accumulated other comprehensive (loss) income	(435)	110
Accumulated deficit	(558,482)	(489,547)
Total stockholders' equity	453,124	354,966
Total liabilities and stockholders' equity	$ 531,625	$ 397,127

See accompanying notes to these financial statements.

Maze Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ 20,000	$ —
Operating expenses:				
Research and development	34,940	28,108	69,088	55,688
General and administrative	13,095	8,366	25,500	16,187
Total operating expenses	48,035	36,474	94,588	71,875
Loss from operations	(48,035)	(36,474)	(74,588)	(71,875)
Other income (expense):				
Interest and other income, net	4,239	2,795	7,450	5,410
Interest expense	(931)	—	(1,797)	—
Total other income, net	3,308	2,795	5,653	5,410
Net loss	$ (44,727)	$ (33,679)	$ (68,935)	$ (66,465)
Net loss per share, basic and diluted:	$ (0.76)	$ (0.77)	$ (1.22)	$ (1.83)
Weighted-average shares of common stock outstanding used to compute net loss per share, basic and diluted:	58,995,934	43,797,421	56,460,660	36,254,828
Comprehensive loss:				
Net loss	$ (44,727)	$ (33,679)	$ (68,935)	$ (66,465)
Other comprehensive loss:				
Net unrealized loss on marketable securities	(300)	—	(545)	—
Comprehensive loss	$ (45,027)	$ (33,679)	$ (69,480)	$ (66,465)

See accompanying notes to these financial statements.

Maze Therapeutics, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share data)

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2024	297,205,041	$ 508,087	2,446,864	$ 2	$ 47,242	$ —	$ (358,427)	$ (311,183)
Issuance of common stock in connection with initial public offering, net of issuance costs of $15,402	—	—	8,750,000	9	124,589	—	—	124,598
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(297,205,041)	(508,087)	32,586,823	33	508,054	—	—	508,087
Exercise of stock options	—	—	13,479	—	126	—	—	126
Stock-based compensation expense	—	—	—	—	3,226	—	—	3,226
Net loss	—	—	—	—	—	—	(32,786)	(32,786)
Balance as of March 31, 2025	—	—	43,797,166	44	683,237	—	(391,213)	292,068
Issuance of common stock upon vesting of restricted stock awards	—	—	2	—	—	—	—	—
Issuance of common stock under the 2025 Employee Stock Purchase Plan	—	—	53,716	—	612	—	—	612
Stock-based compensation expense	—	—	—	—	3,237	—	—	3,237
Net loss	—	—	—	—	—	—	(33,679)	(33,679)
Balance as of June 30, 2025	—	$ —	43,850,884	$ 44	$ 687,086	$ —	$ (424,892)	$ 262,238

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	—	$ —	49,335,551	$ 49	$ 844,354	$ 110	$ (489,547)	$ 354,966
Exercise of stock options	—	—	402,067	1	4,078	—	—	4,079
Issuance of common stock upon vesting of restricted stock awards	—	—	1	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	7,109	—	—	7,109
Net unrealized loss on marketable securities	—	—	—	—	—	(245)	—	(245)
Net loss	—	—	—	—	—	—	(24,208)	(24,208)
Balance as of March 31, 2026	—	—	49,737,619	50	855,541	(135)	(513,755)	341,701
Issuance of common stock and pre-funded warrants to purchase common stock in connection with underwritten registered offering, net of issuance costs of $5,595	—	—	5,540,000	6	144,563	—	—	144,569
Exercise of stock options	—	—	143,698	—	1,696	—	—	1,696
Issuance of common stock under the 2025 Employee Stock Purchase Plan	—	—	83,257	—	998	—	—	998
Stock-based compensation expense	—	—	—	—	9,187	—	—	9,187
Net unrealized loss on marketable securities	—	—	—	—	—	(300)	—	(300)
Net loss	—	—	—	—	—	—	(44,727)	(44,727)
Balance as of June 30, 2026	—	$ —	55,504,574	$ 56	$ 1,011,985	$ (435)	$ (558,482)	$ 453,124

See accompanying notes to these financial statements.

Maze Therapeutics, Inc.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2026	2025
Operating activities		
Net loss	$ (68,935)	$ (66,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	835	1,333
Stock-based compensation expense	16,296	6,463
Non-cash lease expense	1,674	1,543
Amortization of premiums on marketable securities, net	5	—
Amortization of debt discount and debt issuance costs	498	—
Other items, net	18	21
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,536)	(1,750)
Other assets	(412)	18
Accounts payable	418	1,846
Accrued expenses and other liabilities	(90)	(957)
Operating lease liabilities	(1,843)	(1,620)
Long-term liabilities	(1,094)	—
Net cash used in operating activities	(54,166)	(59,568)
Investing activities		
Purchases of marketable securities	(186,031)	—
Maturities of marketable securities	64,000	—
Purchases of property and equipment	(200)	(692)
Net cash used in investing activities	(122,231)	(692)
Financing activities		
Proceeds from underwritten registered offering, net	145,659	—
Payment of underwritten registered offering costs	(1,090)	—
Proceeds from debt issuance, net	39,401	—
Payment of debt issuance costs	(939)	—
Proceeds from exercise of stock option awards	5,775	126
Proceeds from issuance of common stock under the 2025 Employee Stock Purchase Plan	998	612
Payment of offering costs for private placement	(11)	—
Proceeds from initial public offering, net	—	130,200
Payment of initial public offering costs	—	(2,448)
Payment of success fee derivative	—	(500)
Net cash provided by financing activities	189,793	127,990
Net increase in cash, cash equivalents and restricted cash	13,396	67,730
Cash, cash equivalents and restricted cash at beginning of the period	190,335	197,900
Cash, cash equivalents and restricted cash at end of the period	$ 203,731	$ 265,630
Reconciliation to cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 202,643	$ 264,541
Restricted cash	1,088	1,089
Total cash, cash equivalents and restricted cash	$ 203,731	$ 265,630

See accompanying notes to these financial statements.

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

1. Organization and principal activities

Description of business

Maze Therapeutics, Inc., or the Company, is a clinical-stage biopharmaceutical company harnessing the power of human genetics to develop novel, small molecule precision medicines for patients living with kidney and metabolic diseases. The Company was incorporated in Delaware in August 2017 and is located in South San Francisco, California.

2026 Sale Agreement

In February 2026, the Company entered into an Open Market Sale Agreement with Jefferies LLC, serving as sales agent, with respect to an at-the-market offering program pursuant to which the Company may elect to issue and sell shares of its common stock having an aggregate offering price of up to $200.0 million, or the 2026 Sale Agreement, in such quantities and on such minimum price terms as the Company sets from time to time through its sales agent. The Company has agreed to pay its sales agent an aggregate commission equal to up to 3.0% of the gross proceeds of the sales under the agreement. To date, no sales of common stock have occurred under the 2026 Sale Agreement.

Hercules Loan and Security Agreement

In February 2026, the Company entered into a loan and security agreement, or the Hercules Loan Agreement, with certain lenders and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the lenders, which provides for a senior secured term loan facility in an aggregate principal amount of up to $200.0 million, or the Hercules Term Loan Facility. An initial term loan of $40.0 million was funded under the Hercules Loan Agreement and the Hercules Term Loan Facility includes up to six additional term loan tranches providing up to an aggregate $160.0 million in additional loan commitments through February 2031, so long as the Company satisfies certain conditions precedent. The final tranche of $50.0 million is subject to approval by the lenders' investment committee. The Hercules Loan Agreement has a maturity date of February 1, 2031, and may be prepaid at any time, subject to prepayment premiums. See Note 10, Loan and security agreements, for further discussion of the Hercules Loan Agreement.

Liquidity and capital resources

The Company has incurred significant losses and negative cash flows from operations and expects to incur significant and increasing losses as a result of its continued research and development activities. As of June 30, 2026, the Company had an accumulated deficit of $558.5 million. Historically, the Company has financed its operations primarily through issuances of its equity, issuances of convertible promissory notes, debt financings and license agreements. The Company may seek to raise capital through additional term loan tranches pursuant to the Hercules Term Loan Facility, equity financings, including pursuant to the 2026 Sale Agreement, license agreements, or other sources of financing. There can be no assurance that such financings will be available or will be at terms acceptable to the Company.

As of June 30, 2026, the Company had cash, cash equivalents and marketable securities of $494.9 million. The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund the Company's operations for at least one year from the issuance date of these unaudited condensed financial statements.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission, or SEC, Regulation S-X for interim financial information.

These unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 25, 2026, or the 2025 10-K. The condensed balance sheet as of December 31, 2025 was derived from the audited annual financial statements as of and for the period then ended. Certain information and footnote disclosures included in the Company's annual financial statements have been condensed or omitted. The accompanying unaudited condensed financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. All such adjustments are of a normal recurring nature except for the impacts of adopting new accounting standards, if any, discussed below. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

There were no changes to the Company's significant accounting policies during the six months ended June 30, 2026, as described in the Company's audited financial statements as of and for the year ended December 31, 2025 included in the 2025 10-K.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. Assets and liabilities reported in the Company's condensed balance sheet and revenue and expenses reported in the Company's condensed statement of operations and comprehensive loss are affected by estimates and assumptions, which are used for, but are not limited to, measuring and recognizing revenue, including any related constraints, and determining the fair value of assets and liabilities, including income tax uncertainties, the measurement of stock-based compensation expense, and certain accruals. Actual results could differ from such estimates or assumptions.

Segment reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of harnessing its understanding of human genetics and variant functionalization to develop small molecule precision medicines. The Company's chief executive officer, who is the chief operating decision maker, or CODM, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance.

The CODM, in alignment with the Company's overall corporate strategy and goals, analyzes a variety of data to guide segment resource allocation, including program and portfolio scientific data, probability of regulatory and commercial success, and the competitive environment. The CODM also reviews certain financial results included in the segment loss from operations which is reported on the condensed statements of operations and comprehensive loss as total loss from operations. The measure of segment assets is reported on the condensed balance sheets as total assets.

As of June 30, 2026 and December 31, 2025, all of the Company's property and equipment was maintained in the United States. The Company generated no license revenue during the three months ended June 30, 2026 and license revenue of $20.0 million during the six months ended June 30, 2026. No revenue was generated during the three and six months ended June 30, 2025. Segment information for prior periods has been recast to conform to the current year segment information that is provided to the CODM. The following table presents selected financial information with respect to the Company's single operating segment for the three and six months ended June 30, 2026 and 2025 (amounts in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ 20,000	$ —
Direct external research and development expenses by program:				
MZE829	8,444	5,199	15,540	9,823
MZE782	3,177	4,582	8,471	8,948
Discovery research and other programs	3,596	2,742	6,641	5,752
Internal research and development expenses:				
Personnel-related	14,875	10,609	28,866	20,953
Facilities, lab supplies and other	4,848	4,976	9,570	10,212
Total research and development expenses	34,940	28,108	69,088	55,688
General and administrative expenses	13,095	8,366	25,500	16,187
Segment operating expenses	48,035	36,474	94,588	71,875
Segment loss from operations	(48,035)	(36,474)	(74,588)	(71,875)
Segment other income, net	3,308	2,795	5,653	5,410
Segment loss	$ (44,727)	$ (33,679)	$ (68,935)	$ (66,465)

Fair value measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date, and establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

- Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs, other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—Unobservable inputs reflecting the Company's own assumptions incorporated in valuation techniques used to determine fair value. These assumptions are required to be consistent with market participant assumptions that are reasonably available.

For certain financial instruments, including cash and accounts payable, as well as certain accrued liabilities, the recorded amount approximates estimated fair value due to their relatively short maturity period.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid financial instruments with original maturities of 90 days or less at the date of purchase to be cash equivalents. As of June 30, 2026 and December 31, 2025, cash equivalents consisted of money market funds.

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash as of June 30, 2026 and December 31, 2025 included $1.1 million as collateral for a letter of credit related to the Company's headquarters building lease in South San Francisco, California. Restricted cash is classified as a noncurrent asset on the balance sheet. As of June 30, 2026 and December 31, 2025, restricted cash consisted of money market funds.

Deferred offering costs

The Company defers offering costs consisting of legal, accounting and other fees and costs directly associated with in-process equity financings until such financings are consummated. After consummation of the equity financing, these costs are classified in stockholders' equity as a reduction of the additional paid-in capital recorded as a result of the financing. If the in-process financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed statements of operations and comprehensive loss.

Debt issuance costs and debt discount

Debt issuance costs include legal fees, accounting fees and other direct costs incurred in connection with the execution of the Company's debt financings. Debt discount represents costs paid to the lenders. Debt issuance costs and debt discount are deducted from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt using the effective interest method.

Revenue recognition

The Company recognizes revenue in accordance with Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*, or ASC 606. To determine the appropriate amount and timing of revenue to be recognized under this guidance, the Company performs the following steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price, including variable consideration, if any; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the entity satisfies a performance obligation.

The Company has entered into arrangements involving the license of intellectual property. Analyzing the license arrangements to identify performance obligations requires the use of judgment. In arrangements that include the license of intellectual property and other promised services, the Company first identifies if the licenses are distinct from the other promises in the arrangement. For the license of intellectual property that is distinct, the Company recognizes revenue from consideration allocated to the license when the license is transferred and the customer is able to benefit from the license. If the license is not distinct, the license is combined with other services into a single performance obligation and the Company recognizes revenue when (or as) the performance obligation is satisfied. Factors that are considered in evaluating whether a license is distinct from other promised services include, for example, whether the counterparty can benefit from the license without the promised service on its own or with other readily available resources and whether the promised service is expected to significantly modify or customize the intellectual property. Promised goods and services that are not material in the context of the contract are not considered performance obligations.

The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Non-refundable upfront payments are considered fixed consideration and included in the transaction price. At the inception of an arrangement and at each reporting period thereafter, the Company assesses whether it should include development, regulatory, commercial milestones or other forms of variable consideration in the transaction price using the most likely amount method. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. The Company includes the amount of estimated variable consideration, including milestones, in the transaction price to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of the milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect revenue in the period of adjustment. In addition, the Company is eligible to receive certain royalties on net sales of licensed products if successfully commercialized by our licensees. The royalties are dependent on future sales, which are at the full discretion of the licensee. We will recognize sales-based milestone payments in the period in which we achieve the milestone under the sales-based royalty exception allowed under accounting rules. Accordingly, we will apply a constraint to these amounts until the future sales have occurred.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and if the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's balance sheets. If the Company expects to have an unconditional right to receive consideration in the next twelve months, this will be classified in current assets.

Net loss per share

Net loss per share attributable to common stockholders is calculated using the two-class method required for companies with participating securities. The Company considered its convertible preferred stock to be participating securities as the holders were entitled to receive noncumulative dividends in the event that a dividend is paid on common stock.

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period less common shares subject to vesting or forfeiture, without consideration for potentially dilutive securities. In September 2025, the Company entered into a securities purchase agreement, or the Private Placement, pursuant to which the Company issued pre-funded warrants to purchase up to an aggregate of 5,231,090 shares of its common stock at a purchase price of $16.249 per pre-funded warrant, or the 2025 Pre-Funded Warrants. In April 2026, the Company completed an underwritten registered offering, or the Underwritten Registered Offering, pursuant to which the Company issued pre-funded warrants to purchase up to an aggregate of 850,000 shares of its common stock at a purchase price of $23.499 per pre-funded warrant, or the 2026 Pre-Funded Warrants. The 2025 Pre-Funded Warrants and 2026 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.001 per share and do not expire. The pre-funded warrants are considered outstanding upon issuance for the purposes of computing basic net loss per share because the shares are fully vested and exercisable for little consideration after their original issuance date. See Note 6, Capital structure, for further discussion of the Private Placement and Underwritten Registered Offering.

Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and the number of common shares that would be issued assuming exercise and conversion of all potentially dilutive instruments. In calculating diluted net loss per share, the Company applies the treasury stock method to equity awards, if dilutive. Distributed and undistributed earnings are allocated to participating securities based on their participation rights and are subtracted from net income in determining net income attributable to common stockholders for basic and diluted net income per share, only in periods of net income.

Because the Company reported a net loss for the three and six months ended June 30, 2026 and 2025, and the inclusion of the potentially dilutive securities would be antidilutive, diluted net loss per share is the same as basic net loss per share for the periods presented.

Recently adopted accounting pronouncements

In July 2025, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient that assumes that current conditions as of the balance sheet date do not change for the remaining life of the asset in developing reasonable and supportable forecasts during the application of the current expected credit loss model for current accounts receivable and current contract assets arising from transactions under ASC 606. The Company adopted ASU 2025-05 effective January 1, 2026. The Company determined there is no impact to its financial statements from adopting ASU 2025-05 as it does not develop forecasts as part of estimating expected credit losses.

New accounting pronouncements—Not yet adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, which will require additional expense disclosures for all public entities. The amendments require that at each interim and annual reporting period, an entity will disclose certain disaggregated expenses included in each relevant expense caption, as well as the total amount of selling expenses and, in annual periods, an entity's definition of selling expenses. ASU 2024-03 is effective for annual reporting periods beginning with the fiscal year ending December 31, 2027, and interim periods thereafter, with early adoption permitted. The Company expects the adoption of this standard to result in increased disclosures in its financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. ASU 2025-11 improves clarity for interim financial reporting requirements under the existing guidance within ASC 270, Interim Reporting. ASU 2025-11 is effective for public entities with annual periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of ASU 2025-11 on its financial statements and related disclosures.

3. Fair value measurements

The following tables summarize the types of assets measured at fair value on a recurring basis by level within the fair value hierarchy.

	Fair value measurements (in thousands)			
	Total	Level 1	Level 2	Level 3
As of June 30, 2026				
Assets				
Cash equivalents				
Money market funds	$ 81,550	$ 81,550	$ —	$ —
Marketable securities				
U.S. treasury securities	243,324	—	243,324	—
U.S. government agency securities	15,978	—	15,978	—
Commercial paper	17,502	—	17,502	—
Corporate debt securities	15,461	—	15,461	—
Restricted cash	1,088	1,088	—	—
Total assets measured at fair value	$ 374,903	$ 82,638	$ 292,265	$ —
As of December 31, 2025				
Assets				
Cash equivalents				
Money market funds	$ 54,154	$ 54,154	$ —	$ —
Marketable securities				
U.S. treasury securities	139,453	—	139,453	—
U.S. government agency securities	23,476	—	23,476	—
Commercial paper	5,876	—	5,876	—
Corporate debt securities	1,979	—	1,979	—
Restricted cash	1,088	1,088	—	—
Total assets measured at fair value	$ 226,026	$ 55,242	$ 170,784	$ —

There were no transfers between Level 1, 2, or 3 during the three and six months ended June 30, 2026 and 2025.

4. Marketable securities

All marketable securities were considered available-for-sale as of June 30, 2026 and December 31, 2025. On a recurring basis, the Company records its marketable securities at fair value using Level 1 or Level 2 inputs as discussed in Note 3, Fair value measurements. The amortized cost, unrealized holding gains, unrealized holding losses and fair value of the Company's marketable securities by major security type as of June 30, 2026 and December 31, 2025 are summarized in the table below:

	As of June 30, 2026 (in thousands)			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Marketable securities, current				
U.S. treasury securities	$ 159,740	$ 2	$ (239)	$ 159,503
U.S. government agency securities	15,986	—	(8)	15,978
Commercial paper	17,527	—	(25)	17,502
Corporate debt securities	15,492	—	(31)	15,461
Total short-term marketable securities	208,745	2	(303)	208,444
Marketable securities, non-current				
U.S. treasury securities	83,955	3	(137)	83,821
Total long-term marketable securities	83,955	3	(137)	83,821
Total	$ 292,700	$ 5	$ (440)	$ 292,265

	December 31, 2025 (in thousands)			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Marketable securities, current				
U.S. treasury securities	$ 121,246	$ 93	$ —	$ 121,339
U.S. government agency securities	23,467	9	—	23,476
Commercial paper	5,874	2	—	5,876
Corporate debt securities	1,979	—	—	1,979
Total short-term marketable securities	152,566	104	—	152,670
Marketable securities, non-current				
U.S. treasury securities	18,108	6	—	18,114
Total long-term marketable securities	18,108	6	—	18,114
Total	$ 170,674	$ 110	$ —	$ 170,784

Interest receivable as of June 30, 2026 and December 31, 2025 was $2.8 million and $1.5 million, respectively, and is recorded as a component of prepaid expenses and other current assets on the Company's condensed balance sheets.

As of June 30, 2026, 66 of the Company's marketable securities were in an unrealized loss position, and no marketable securities had been in continuous unrealized loss positions for 12 months or longer. The Company has not recognized an allowance for credit losses as of June 30, 2026 or December 31, 2025. The Company determined that it has the ability and intent to hold all marketable securities that have been in a continuous unrealized loss position until their maturity or recovery of their amortized cost. Further, a majority of the Company's investments were held in U.S. government securities, and the remainder were held with investment grade, high credit quality institutions. Moreover, the Company continues to receive payments of interest and principal as they become due, and the Company's expectation is that those payments will continue to be received timely. Based on this evaluation, as of June 30, 2026, the Company determined that unrealized losses of its marketable securities were primarily attributable to changes in interest rates and non-credit related factors. As of June 30, 2026, all of the Company's marketable securities have a remaining contractual maturity of less than two years.

5. Balance sheet components

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	As of June 30, 2026	As of December 31, 2025
	(in thousands)	
Accrued compensation expenses	$ 6,927	$ 10,853
Accrued research and development expenses	7,009	4,305
Accrued professional expenses	1,530	660
Other	400	149
Total accrued expenses and other current liabilities	$ 15,866	$ 15,967

6. Capital structure

2026 Sale Agreement

In February 2026, the Company entered into the 2026 Sale Agreement. See Note 1, Organization and principal activities, for further discussion of the 2026 Sale Agreement.

Private placement

In September 2025, the Company completed the Private Placement, pursuant to which the Company issued and sold an aggregate of 4,000,002 shares of its common stock at a purchase price of $16.25 per share and the 2025 Pre-Funded Warrants to purchase up to an aggregate of 5,231,090 shares of its common stock at a purchase price of $16.249 per pre-funded warrant, resulting in net proceeds of approximately $141.3 million, after deducting placement fees and other offering expenses paid by the Company of approximately $8.7 million. The 2025 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.001 per share each and do not expire. The 2025 Pre-Funded Warrants provide that each holder of the 2025 Pre-Funded Warrants does not have the right to exercise any portion of its 2025 Pre-Funded Warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99%, at the holder's election, of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of the 2025 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to the Company. For the three and six months ended June 30, 2026, no 2025 Pre-Funded Warrants were exercised, and as of June 30, 2026, 2025 Pre-Funded Warrants to purchase 4,331,090 shares of the Company's common stock remained outstanding.

Underwritten Registered Offering

In April 2026, the Company completed the Underwritten Registered Offering, pursuant to which the Company issued and sold an aggregate of 5,540,000 shares of its common stock at a purchase price of $23.50 per share and the 2026 Pre-Funded Warrants to purchase up to an aggregate of 850,000 shares of its common stock at a purchase price of $23.499 per pre-funded warrant, resulting in net proceeds of approximately $144.6 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company of approximately $5.6 million. The 2026 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.001 per share each and do not expire. The 2026 Pre-Funded Warrants provide that each holder of the 2026 Pre-Funded Warrants does not have the right to exercise any portion of its 2026 Pre-Funded Warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of the 2026 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to the Company. For the three and six months ended June 30, 2026, no 2026 Pre-Funded Warrants were exercised, and as of June 30, 2026, 2026 Pre-Funded Warrants to purchase 850,000 shares of the Company's common stock remained outstanding.

Upon the issuance of the 2025 Pre-Funded Warrants and the 2026 Pre-Funded Warrants, the Company evaluated the warrant terms to determine the appropriate accounting and classification pursuant to Accounting Standards Codification 480, *Distinguishing Liabilities from Equity*, and Accounting Standards Codification 815, *Derivatives and Hedging*. Warrants are classified as liabilities when the warrant terms allow settlement of the warrant exercise in cash and classified as equity when the warrant terms only allow settlement in shares of common stock. The terms of the 2025 Pre-Funded Warrants and the 2026 Pre-Funded Warrants include certain provisions related to fundamental transactions and a cashless exercise provision in the event registered shares are not available, and do not include any mandatory redemption provisions. Based on its evaluation, the Company concluded the 2025 Pre-Funded Warrants and the 2026 Pre-Funded Warrants should be classified as equity with no subsequent remeasurement as long as such warrants continue to be classified as equity.

7. Equity incentive plans and stock-based compensation expense

2025 Equity Incentive Plan

The Company's board of directors, or Board of Directors, and stockholders approved the 2025 Equity Incentive Plan, or 2025 Plan, which became effective on January 29, 2025. The 2025 Plan replaced the 2019 Equity Incentive Plan, or 2019 Plan, and upon its effectiveness, the Company ceased granting awards under the 2019 Plan. The 2025 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The Company initially reserved 5,300,000 shares of its common stock under the 2025 Plan plus those shares of common stock previously reserved but unissued under the 2019 Plan. Any outstanding awards granted under the 2019 Plan will remain subject to the terms of the 2019 Plan and applicable award agreements. The number of shares reserved for issuance under the 2025 Plan will increase automatically on January 1st each year from 2026 through 2035 by the number of shares equal to the lesser of 5% of the sum of (a) the total number of outstanding shares of all classes of the Company's common stock plus (b) the total number of shares of the Company's common stock subject to pre-funded warrants (if any) and (c) the total number of shares of the Company's common stock issuable upon conversion of preferred stock (if any), in each case as of the immediately preceding December 31st, or a number as may be determined by the Board of Directors or compensation committee thereof. Accordingly, the Company's common stock reserved for future issuance under the 2025 Plan was increased by 2,683,332 shares on January 1, 2026.

As of June 30, 2026, there was an aggregate of 6,125,834 options outstanding under the 2019 Plan and 2025 Plan and 1,033,730 restricted stock units, or RSUs, outstanding under the 2025 Plan.

2025 Employee Stock Purchase Plan

The Board of Directors and stockholders approved the 2025 Employee Stock Purchase Plan, or 2025 ESPP, which became effective on January 30, 2025. The number of shares initially available for issuance pursuant to the 2025 ESPP was 450,000 shares. The purchase price of common stock purchased under the 2025 ESPP is equal to 85% of the lesser of the fair market value of the Company's common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period. The aggregate number of shares reserved for sale under the 2025 ESPP will increase automatically on January 1st each year from 2026 through 2035 by the number of shares equal to 1% of the sum of (a) the total number of outstanding shares of all classes of the Company's common stock plus (b) the total number of shares of the Company's common stock subject to pre-funded warrants (if any) and (c) the total number of shares of the Company's common stock issuable upon conversion of preferred stock (if any), in each case outstanding as of the immediately preceding December 31st, provided that the Board of Directors or compensation committee may in its sole discretion reduce the amount of the increase in any particular calendar year. Accordingly, the number of shares reserved for future issuance under the 2025 ESPP was increased by 536,666 shares on January 1, 2026. During the three and six months ended June 30, 2026, 83,257 shares were issued under the 2025 ESPP and 53,716 shares were issued under the 2025 ESPP during the same periods in 2025.

Stock-based compensation expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed statements of operations and comprehensive loss during the three and six months ended June 30, 2026 and 2025:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Research and development	$ 4,603	$ 1,998	$ 8,131	$ 3,856
General and administrative	4,584	1,239	8,165	2,607
Total stock-based compensation expense	$ 9,187	$ 3,237	$ 16,296	$ 6,463

As of June 30, 2026, there was $55.7 million of total unrecognized compensation cost related to unvested options for which the cost is expected to be recognized over a weighted-average period of 2.70 years. As of June 30, 2026, there was $1.4 million of total unrecognized compensation cost related to the 2025 ESPP for which the cost is expected to be recognized over a weighted-average period of 1.12 years.

Total stock-based compensation expense related to RSUs recognized during the three and six months ended June 30, 2026 was $3.0 million and $5.2 million, respectively, and is included in the stock-based compensation expense table above. No stock-based compensation expense related to RSUs was recognized during the three and six months ended June 30, 2025. As of June 30, 2026, there was $27.0 million of total unrecognized compensation cost related to outstanding RSUs that is expected to be recognized over a weighted average period of 2.26 years.

8. License agreements

Trace License Agreement

In March 2024, the Company entered into an exclusive license agreement with Trace Neuroscience, Inc., or Trace, pursuant to which the Company granted an exclusive worldwide license to a discovery research program targeting UNC13A for the treatment of amyotrophic lateral sclerosis, or the Trace License Agreement. As consideration for the licensed rights and the transfer of know-how and materials, the Company received an upfront payment of $15.0 million in April 2024. Thereafter, the Company is entitled to potential subsequent payments of up to an aggregate of $80.0 million based on development and regulatory milestones and up to an aggregate of $250.0 million based on sales milestones. The Company is also entitled to tiered royalties ranging from percentages in the low single-digits to sub-teens on net sales of any licensed product if successfully commercialized.

The Company assessed the Trace License Agreement in accordance with ASC 606 and concluded that it was a contract with a customer. The Company determined that there is one performance obligation relating to the license to the UNC13A discovery program, including the underlying know-how and certain related materials, and that the transaction price consisted of the $15.0 million non-refundable upfront cash payment. The potential future development and regulatory milestones represent variable consideration and were constrained, as it was concluded that it was not probable that a significant reversal in cumulative revenue recognized will not occur and therefore not included in the transaction price as of June 30, 2026. Potential sales milestones and royalties on net product sales will be recognized in the same period that the underlying net product sales occur as they were determined to relate to the license. The $15.0 million transaction price was recorded as license revenue in the statements of operations and comprehensive loss during the year ended December 31, 2024, at the point in time when control of the license and related know-how was transferred to Trace.

Shionogi License Agreement

In March 2024, the Company entered into an exclusive license agreement with Shionogi & Company, Ltd., or Shionogi, pursuant to which the Company granted Shionogi an exclusive, worldwide, sublicensable license to research, develop, manufacture and commercialize MZE001 and certain other small molecule compounds modulating glycogen synthase 1, or the Shionogi License Agreement. As consideration for the licensed rights and the transfer of know-how and materials, the Company received an upfront payment of $150.0 million in May 2024 upon the effectiveness of the Shionogi License Agreement. The Shionogi License Agreement also requires that Shionogi pay the Company up to $275.0 million in the aggregate in milestone payments upon the completion of certain clinical and regulatory milestones and up to $330.0 million in the aggregate in milestone payments if certain sales milestones are achieved. In March 2026, a $20.0 million clinical development milestone was achieved upon dosing of the first patient in Shionogi's Phase 2 study of MZE001 in patients with Pompe disease. The Company recognized $20.0 million as license revenue in the condensed statements of operations and comprehensive loss for the three months ended March 31, 2026 in connection with the achievement of the clinical development milestone and payment for the development milestone was received in April 2026. The Shionogi License Agreement also requires that Shionogi pay the Company tiered royalties ranging from percentages in the low double-digits to twenty on net sales of licensed products, subject to certain deductions.

The Company assessed the Shionogi License Agreement in accordance with ASC 606 and concluded that it was a contract with a customer. The Company determined that there is one performance obligation relating to the license to the MZE001 program, including the underlying know-how and certain related materials, and that the transaction price at the inception of the Shionogi License Agreement consisted of the $150.0 million non-refundable upfront cash payment, which was recognized as license revenue in the statements of operations and comprehensive loss during the year ended December 31, 2024 at the point in time when control of the license and related know-how and materials was transferred to Shionogi. The $20.0 million clinical development milestone was recognized as license revenue upon its achievement in March 2026. The remaining potential clinical and regulatory milestones represent variable consideration and were constrained as it was concluded that it was not probable that a significant reversal in cumulative revenue recognized will not occur and therefore are not included in the transaction price as of June 30, 2026. Potential sales milestones and royalties on net product sales will be recognized in the same period that the underlying net product sales occur as they were determined to relate to the license.

Neurocrine License Agreement

In May 2024, the Company entered into an exclusive license agreement with Neurocrine Biosciences, Inc., or Neurocrine, pursuant to which the Company granted Neurocrine an exclusive worldwide license to a discovery research program targeting ATXN2, or the Neurocrine License Agreement. As consideration for the licensed rights and the transfer of know-how and materials, the Company received an upfront payment of $2.5 million in June 2024. Thereafter, the Company is entitled to potential subsequent payments of up to an aggregate of $24.8 million based on research and development milestones and up to an aggregate of $175.0 million based on sales milestones. The Company is also entitled to tiered royalties ranging in the sub-single-digit to low single-digit percentages on net sales of any licensed product if successfully commercialized.

The Company assessed the Neurocrine License Agreement in accordance with ASC 606 and concluded that it was a contract with a customer. The Company determined that there is one performance obligation relating to the license to the ATXN2 discovery program, including the underlying know-how and certain related materials, and that the transaction price consisted of the $2.5 million upfront cash payment. The potential research and development milestones represent variable consideration and were constrained as it was concluded that it was not probable that a significant reversal in cumulative revenue recognized will not occur and therefore not included in the transaction price as of June 30, 2026. Potential sales milestones and royalties on net product sales will be recognized in the same period that the underlying net product sales occur as they were determined to relate to the license. The $2.5 million transaction price was recorded as license revenue in the statements of operations and comprehensive loss during the year ended December 31, 2024, at the point in time when control of the license and the related know-how and materials was transferred to Neurocrine.

In August 2026, the Company received notice from Neurocrine of its intent to terminate the Neurocrine License Agreement, effective November 2026, pursuant to the terms of the agreement. The Company does not expect the termination to have a material impact on its previously recognized license revenue.

9. Commitments and contingencies

Legal proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. No contingent liabilities have been recorded as of June 30, 2026 and December 31, 2025.

Indemnification

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Consortium agreements

The Company has entered into a consortium agreement and certain related amended agreements with the University of Helsinki and other parties for access to a collaborative pre-competitive research project. The project aims to collect genomic information from patient samples in biobanks across Finland to which the Company is granted access. Under the agreement, the Company is obligated to pay certain installments through the year 2027. As of June 30, 2026, the Company is obligated to pay approximately $3.5 million under this agreement.

10. Loan and security agreements

Hercules Loan and Security Agreement

On February 4, 2026, or the Closing Date, the Company entered into the Hercules Loan Agreement. The Hercules Loan Agreement provides for a senior secured term loan facility in an aggregate principal amount of up to $200.0 million, or the Hercules Term Loan Facility. An initial term loan of $40.0 million, or the Tranche 1A Loan, was funded under the Hercules Term Loan Facility on the Closing Date. In addition to the Tranche 1A Loan, the Hercules Term Loan Facility includes up to six additional term loan tranches providing up to an aggregate $160.0 million in additional loan commitments (collectively with the Tranche 1A Loan, the Term Loans). The final tranche of $50.0 million will be available subject to future approval by the lenders' investment committee. The tranches will be available up to 60 months after the Closing Date, so long as the Company satisfies certain conditions precedent, including compliance with financial covenants, the continued accuracy of the representations and warranties provided in the Hercules Loan Agreement and satisfaction of certain performance and financing milestones.

The Hercules Term Loan Facility has a maturity date of February 1, 2031, or the Maturity Date. Upon repayment of the Term Loans (whether at the Maturity Date or upon earlier prepayment), the Company is required to pay an exit fee, or the End of Term Charge, equal to (i) 3.95% of the principal amount being repaid, if repaid on or within 24 months of the Closing Date, (ii) 5.75% of the principal amount being repaid, if repaid more than 24 months after the Closing Date and on or within 48 months of the Closing Date, and (iii) 6.45% of the principal amount being repaid, if repaid thereafter. In addition, the Hercules Loan Agreement required the Company to pay a facility charge of 1.00% of the funded Tranche 1A Loan, which was due at the Closing Date, and requires a facility charge of 1.00% for each subsequent term loan tranche at the time such tranche is funded. The Company also paid a draw down fee of 2.00% of the funded Tranche 1A Loan and is required to pay subsequent draw down fees equal to 2.00% of each subsequent term loan tranche at the time such tranche is funded.

The Hercules Term Loan Facility will accrue interest at an annual rate determined by reference to the Prime Rate as reported in the Wall Street Journal, with interest rate floors that range from 7.95% (with respect to the Tranche 1A Loan funded on the Closing Date, among other tranches) to 9.25% depending on the tranche. The Hercules Term Loan Facility provides for payment of interest only until (a) 48 months after the Closing Date or (b) if certain performance and financing milestones are satisfied, 60 months after the Closing Date. Accrued interest on the Term Loans is payable on the first business day of each month. Upon an Event of Default (as defined in the Hercules Loan Agreement), the interest rate will automatically increase by an additional 4.00% per annum.

The Term Loans may be prepaid at any time, subject to a prepayment premium equal to (i) 3.00% of the aggregate outstanding principal amount being prepaid, if prepaid on or within 12 months of the Closing Date; (ii) 2.00% of the aggregate outstanding principal amount being prepaid, if prepaid more than 12 months after the Closing Date and on or within 24 months of the Closing Date; (iii) 1.00% of the aggregate outstanding principal amount being prepaid, if prepaid more than 24 months after the Closing Date and on or within 36 months of the Closing Date; and (iv) 0.00% thereafter, and the End of Term Charge described above.

Pursuant to the Hercules Loan Agreement, all of the Company's obligations under the Hercules Loan Agreement are secured by a first lien perfected security interest on substantially all of the Company's existing and after-acquired assets, subject to customary exceptions.

The Hercules Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. In addition, unless either (i) the Company's market capitalization is greater than or equal to $450.0 million and an aggregate of no more than $85.0 million in principal amount is outstanding under the Term Loans or (ii) the Company's market capitalization is greater than or equal to $750.0 million, the Company must at all other times maintain unrestricted cash and cash equivalents of at least 50% of the outstanding loan amount, decreasing to 40% and 35% upon satisfaction of certain performance and financing milestones.

The Hercules Loan Agreement also contains certain customary Events of Default which include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts, certain material regulatory-related events and events constituting a change of control. The occurrence of an Event of Default could result in, among other things, the declaration that all outstanding principal and interest under the Hercules Term Loan Facility are immediately due and payable in whole or in part. As of June 30, 2026, the Company was in compliance with the covenants under the Hercules Loan Agreement.

The Company accounted for the End of Term Charge, facility charge, and other direct costs incurred in connection with the Tranche 1A Loan of the Hercules Loan Agreement as debt discount and issuance costs, and they are being amortized over the term of the loan using the effective interest method. The weighted-average effective interest rate on the Tranche 1A Loan is 9.77%.

The Company incurred interest expense on the Tranche 1A Loan, including the amortization of debt discount and issuance costs, of $0.9 million and $1.8 million during the three and six months ended June 30, 2026, respectively.

The Tranche 1A Loan consists of the following:

	As of June 30, 2026
	(in thousands)
Term loan principal amount	$ 40,000
End of term charge	2,580
Unamortized discount and issuance costs	(3,620)
Total term loan	38,960
Less: current portion of term loan	—
Total term loan, net of current portion	$ 38,960

Future principal loan payments on the currently outstanding Tranche 1A Loan as June 30, 2026 are as follows:

Year Ending December 31,	Amount (in thousands)
2026	$ —
2027	—
2028	—
2029	—
2030	33,602
2031	6,398
Total future principal payments	40,000
Add: end of term charge	2,580
Less: unamortized discount and issuance costs	(3,620)
Less: current portion of term loan	—
Total term loan, net of current portion	$ 38,960

Banc of California Loan and Security Agreement

In connection with the Company's entry into the Hercules Loan Agreement, the loan and security agreement for a $50.0 million revolving line of credit with Banc of California dated June 27, 2022, as amended in March 2025, was terminated, effective as of February 2, 2026, and the lender's security interest in the Company's assets and property was released.

11. Related party transactions

The Company has paid fees to its founders and certain board members in exchange for consulting services. During the three and six months ended June 30, 2026 and 2025, the Company recorded an immaterial amount of such fees in general and administrative expenses in the condensed statements of operations and comprehensive loss.

12. Net loss per share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (44,727)	$ (33,679)	$ (68,935)	$ (66,465)
Denominator:				
Weighted-average shares of common stock outstanding	54,030,711	43,807,793	51,815,909	36,265,200
Add: weighted-average shares of common stock to be issued upon exercise of pre-funded warrants	4,975,595	—	4,655,123	—
Less: weighted-average shares of common stock subject to repurchase	(10,372)	(10,372)	(10,372)	(10,372)
Weighted-average shares of common stock outstanding used in the calculation of net loss per share, basic and diluted	58,995,934	43,797,421	56,460,660	36,254,828
Net loss per share, basic and diluted	$ (0.76)	$ (0.77)	$ (1.22)	$ (1.83)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive are as follows:

	Six Months Ended June 30,	
	2026	2025
Shares subject to outstanding stock options	6,125,834	5,347,639
Shares subject to outstanding restricted stock units	1,033,730	—
Unvested restricted stock subject to repurchase	10,372	10,372
Total	7,169,936	5,358,011

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q; and the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2025 as filed with the SEC on March 25, 2026, or 2025 Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company harnessing the power of human genetics to develop novel, small molecule precision medicines for patients living with kidney and metabolic diseases. We are advancing a pipeline using our Compass platform, which allows us to identify and characterize genetic variants associated with health and disease and then determine how these drive risk for and protection against disease in specific patient groups through a process we refer to as variant functionalization. Our Compass platform has been purpose-built to inform all phases of our drug discovery and development process through clinical trial design. We are currently advancing two wholly-owned clinical programs, MZE829 and MZE782, each of which represents a novel precision medicine-based approach. Our goal is to bring novel precision medicines to patients with kidney and metabolic diseases, which is where we believe we can maximize our impact on human health.

Our most advanced program, MZE829, is an oral, small molecule, dual-mechanism inhibitor of apolipoprotein L1, or APOL1, for the treatment of patients with APOL1-mediated kidney disease, or AMKD, a genetically defined sub-set of chronic kidney disease, or CKD, for which there is no approved treatment today. We initiated a Phase 2 trial of MZE829 in November 2024 and dosed our first patient in February 2025. In March 2026, we announced positive topline clinical proof of concept data from our Phase 2 trial of MZE829 in patients with AMKD, in which we enrolled 15 patients. The results demonstrated that treatment with MZE829 led to a clinically meaningful mean reduction in proteinuria, as measured by urinary albumin-to-creatinine ratio. MZE829 was generally well tolerated, with no serious adverse events or severe treatment-related adverse events reported. We plan to continue enrollment in the Phase 2 trial and anticipate reporting additional data from this trial in late 2026 or early 2027. In addition, we plan to initiate a pivotal trial of MZE829 in the first half of 2027, subject to regulatory feedback.

Our second program, MZE782, is an oral, small molecule inhibitor for the treatment of patients with phenylketonuria, or PKU, an inherited metabolic disorder, and for the treatment of patients with CKD. In September 2025, we reported results from our Phase 1 clinical trial of MZE782, in which we enrolled 112 healthy adult volunteers. MZE782 was well tolerated across all doses in all cohorts and demonstrated a favorable pharmacokinetics profile after single and multiple oral doses. MZE782 produced dose-dependent increases in 24-hour urinary excretion of the neutral amino acids phenylalanine and glutamine across both single ascending dose and multiple ascending dose cohorts, confirming target engagement and SLC6A19 inhibition. We also observed dose-dependent changes in estimated glomerular filtration rate in healthy individuals with MZE782, similar to those seen with SGLT2 inhibitors, suggesting a potential beneficial effect on kidney physiology in CKD patients. In August 2026, we announced that the Phase 2 proof-of-concept trial of MZE782 in patients with PKU has initiated and we anticipate reporting topline data from this trial in 2027. We plan to initiate a Phase 2 proof-of-concept trial of MZE782 in patients with CKD in the first half of 2027.

Since our inception, we have focused substantially all of our efforts and financial resources on research and development activities for our programs and on establishing arrangements and collaborations with third parties for the development of our therapeutic candidates. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity and convertible promissory notes, debt financing, as well as one-time, nonrefundable upfront payments we received pursuant to the license agreements we entered into with several biotechnology companies in 2024, including the exclusive license agreement with Shionogi & Company, Ltd., or Shionogi. We do not expect to generate any revenue from commercial sales for the foreseeable future. We expect to continue incurring significant operating losses for the foreseeable future due to the cost of research and development, clinical trials, preclinical studies and the regulatory approval process for our therapeutic candidates.

We have incurred significant losses and negative cash flows from operations and we expect to incur significant and increasing losses for the foreseeable future as a result of our continued research and development activities. During the three and six months ended June 30, 2026, we incurred a net loss of $44.7 million and $68.9 million, respectively. During the three and six months ended June 30, 2025, we incurred a net loss of $33.7 million and $66.5 million, respectively. As of June 30, 2026, we had an accumulated deficit of $558.5 million and do not expect positive cash flows from operations for the foreseeable future. Our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities, as well as upon revenue from our license agreements. We expect our research and development expenses to significantly increase in connection with the conduct of planned clinical trials for our lead programs, MZE829 and MZE782, further development of our Compass platform, planned preclinical studies, and potential Investigational New Drug Applications, or INDs, and clinical trials for future therapeutic candidates. We will also incur substantial additional expenses as we seek to expand our intellectual property portfolio, including through potential in-licensing opportunities, and hire additional personnel as we scale up our operations. In addition, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2026, we had cash, cash equivalents and marketable securities of $494.9 million. Since our inception, we have financed our operations primarily through issuances of our equity and convertible promissory notes, debt financing, and license agreements with biotechnology companies.

We will require substantial additional capital to develop our therapeutic candidates and fund operations for the foreseeable future. Until such time as we can generate sufficient revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations and licensing agreements.

Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our clinical and preclinical development, research and development programs, our commercialization plans or other operations. The amount and timing of our future funding requirements will depend on many factors including the pace and results of our development efforts. We cannot assure that we will ever be profitable or generate positive cash flows from operating activities.

We selectively pursue strategic collaborations related to the development of certain targets, therapeutic programs, or disease areas where we believe third-party expertise or resources could be beneficial. In 2020, we formed a spin-out company, Broadwing Bio LLC, or Broadwing, with Alloy Therapeutics, Inc., or Alloy, to develop therapeutic antibody therapies for ANGPTL7 and another undisclosed target in ophthalmic diseases, informed by our Compass platform. As of June 30, 2026, we owned approximately 48% of the outstanding equity of Broadwing, and we expect our ownership to be significantly diluted upon the conversion of outstanding convertible notes issued by Broadwing. We retain certain opt-in rights to jointly develop and commercialize certain therapeutic candidates developed through Broadwing with Alloy. We are not involved in the development of Broadwing's therapeutic candidate.

Exclusive license agreement with Shionogi

In March 2024, we entered into an exclusive license agreement, or the License Agreement, with Shionogi, pursuant to which we granted Shionogi an exclusive, worldwide, sublicensable license to research, develop, manufacture and commercialize MZE001 and certain other small molecule compounds modulating glycogen synthase 1, or the Licensed Products. As consideration for the licensed rights and the transfer of know-how and materials, we received an upfront payment of $150.0 million in May 2024 upon the effectiveness of the License Agreement. The License Agreement also requires that Shionogi pay us up to $275.0 million in the aggregate in milestone payments upon the completion of certain clinical development and regulatory milestones and up to $330.0 million in the aggregate in milestone payments if certain sales milestones are achieved. In April 2026, we received $20.0 million following the achievement of a clinical development milestone upon dosing of the first patient in Shionogi's Phase 2 study of MZE001 in patients with Pompe disease. The License Agreement also requires that Shionogi pay us tiered royalties ranging from percentages in the low double-digits to twenty on net sales of Licensed Products, subject to certain deductions.

The License Agreement will expire on a Licensed-Product by Licensed-Product and country-by-country basis upon the expiration of the royalty term for such Licensed Product, which will be the latest of the date when there are no remaining valid claims covering the applicable Licensed Product, the expiration of regulatory exclusivity for the applicable Licensed Product, or 11 years after the first commercial sale of the applicable Licensed Product, subject to earlier termination by the parties. As of June 30, 2026, we estimate that the last patent right for the only currently issued patent licensed under the License Agreement will expire in 2042, without giving effect to any potential patent term extensions, patent term adjustments**,** or future patents that may or may not issue with respect to the Licensed Products. Upon expiration of the License Agreement, the licenses granted to Shionogi will become fully paid-up, perpetual, irrevocable and royalty-free. Shionogi may terminate the License Agreement for convenience following a notice period and either party may terminate the License Agreement for bankruptcy or an uncured material breach. Upon termination of the License Agreement by Shionogi for convenience or by us for Shionogi's bankruptcy or uncured material breach, Shionogi will grant us a non-exclusive, worldwide license under certain patent rights and know-how controlled by Shionogi as of the effective date of termination, solely as necessary to research, develop, manufacture and commercialize the Licensed Products in any field, and Shionogi will assign to us all regulatory materials and regulatory approvals relating to the Licensed Products. In consideration for these reversion rights, we would be required to pay to Shionogi reversion royalties on any sales of the Licensed Products determined based on the stage of clinical development of the applicable Licensed Product at the time of termination, ranging from percentages in the low-to-mid single digits if termination occurs on or after the achievement of certain Phase 2 clinical trial milestones and high single digit to mid-teens if termination occurs on or after the achievement of certain Phase 3 clinical milestones. Our obligation to pay these reversion royalties would expire on a Licensed-Product by Licensed-Product and country-by-country basis upon the latest of the date when there are no remaining valid claims covering the applicable Licensed Product, the expiration of regulatory exclusivity for the applicable Licensed Product, or ten years after the first commercial sale of the applicable Licensed Product.

Components of results of operations

License revenue

We recognize revenue from the various license agreements we have entered into as the identified performance obligations under these arrangements are satisfied. We are also eligible to receive future non-refundable, non-creditable milestone payments upon the achievement of certain development, regulatory, and commercial milestones. Additionally, we are also eligible to receive certain royalties on net sales of products developed under the license agreements.

Operating expenses

Our operating expenses since inception have consisted solely of research and development expenses and general and administrative expenses.

Research and development expenses

Our research and development expenses consist primarily of external and internal expenses incurred in connection with our research activities and preclinical and clinical development programs. These expenses include, but are not limited to:

- salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- fees paid to vendors that conduct certain research and development activities on our behalf;
- fees paid to contract manufacturing organizations, or CMOs, in connection with the production of research products and clinical trial materials;
- fees paid to clinical research organizations, or CROs, in connection with clinical trials as well as preclinical and toxicology studies;
- other expenses associated with laboratory supplies and other materials;
- professional service fees for consulting and related services; and
- facility costs, depreciation, and other expenses, which include expenses for rent and maintenance of facilities.

We recognize research and development expenses as incurred. Nonrefundable advance payments for goods or services to be used in future research and development activities are capitalized and expensed as the related goods are received or services are performed. Direct external research and development costs are recorded to the specific programs they support. Internal research and development costs, including personnel, facility and laboratory supplies, are utilized across multiple research and development programs and are therefore not directly attributable to any single program.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, MZE829, MZE782 and any of our other potential therapeutic candidates.

Our research and development expenses may vary significantly based on a variety of factors, such as:

- the timing and progress of clinical development activities for our therapeutic candidates;
- the timing and progress of preclinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to hire clinical, regulatory, manufacturing, quality assurance and scientific personnel;
- potential additional trials requested by regulatory agencies;
- the costs and fees associated with the discovery, acquisition or in-license of our products or technologies, including to maintain and expand our Compass platform;
- our ability to establish clinical manufacturing capabilities or secure adequate supply of product from third-party manufacturers;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

A change in the outcome of any of these and other variables with respect to the development of any of our therapeutic candidates could significantly change the costs and timing associated with the development of such therapeutic candidate. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we continue to identify and develop potential additional therapeutic candidates and as our existing therapeutic candidates, including MZE829 and MZE782, move into later stages of clinical development, which typically have higher development costs than those in earlier stages of clinical development or preclinical development due to the increased size and duration of later-stage clinical trials.

The process of conducting the necessary preclinical and clinical research and development to obtain regulatory approval is costly and time-consuming and the successful development of our therapeutic candidates is highly uncertain. The actual probability of success for our therapeutic candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our therapeutic candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our therapeutic candidates' development, which could increase our research and development expenses.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation expense, for personnel in executive, finance, accounting, corporate development, and other administrative functions. General and administrative expenses also include legal fees, professional fees paid for accounting, auditing, consulting, tax, and investor relations services, insurance costs, and facility costs not otherwise included in research and development expenses, and public company expenses such as costs associated with compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and Nasdaq.

We expect that our general and administrative expenses will continue to increase significantly in the foreseeable future as additional administrative personnel and services are required to manage these functions associated with being a public company and as our pipeline of therapeutic candidates expands.

Total other income, net

Total other income, net, primarily consists of interest income earned on our cash, cash equivalents and marketable securities and interest expense recognized on the loan and security agreement, or the Hercules Loan Agreement, with certain lenders and Hercules Capital, Inc. We expect total other income, net to increase as a result of additional interest income on the proceeds received from the initial term loan of $40.0 million under the Hercules Loan Agreement and the net proceeds of approximately $144.6 million from the underwritten registered offering completed in April 2026, which is expected to be partially offset by interest expense recognized on the Hercules Loan Agreement. However, other income, net may vary each reporting period depending on our average cash deposits, money market fund and other investment balances during the period, prevailing market interest rates and the amount of interest expense incurred under the Hercules Loan Agreement.

Results of operations

Comparisons of the three and six months ended June 30, 2026 and 2025

	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
		(in thousands)			(in thousands)	
License revenue	$ —	$ —	$ —	$ 20,000	$ —	$ 20,000
Operating expenses:						
Research and development	34,940	28,108	6,832	69,088	55,688	13,400
General and administrative	13,095	8,366	4,729	25,500	16,187	9,313
Total operating expenses	48,035	36,474	11,561	94,588	71,875	22,713
Loss from operations	(48,035)	(36,474)	(11,561)	(74,588)	(71,875)	(2,713)
Other income (expense):						
Interest and other income, net	4,239	2,795	1,444	7,450	5,410	2,040
Interest expense	(931)	—	(931)	(1,797)	—	(1,797)
Total other income, net	3,308	2,795	513	5,653	5,410	243
Net loss	$ (44,727)	$ (33,679)	$ (11,048)	$ (68,935)	$ (66,465)	$ (2,470)

License revenue

We recognized no license revenue for the three months ended June 30, 2026 and $20.0 million in license revenue for the six months ended June 30, 2026. We recognized no license revenue for the three and six months ended June 30, 2025. License revenue recognized in 2026 was related to achievement of a clinical development milestone upon dosing of the first patient in Shionogi's Phase 2 study of MZE001 in patients with Pompe disease under the License Agreement with Shionogi.

Research and development expenses

Research and development expenses were $34.9 million and $28.1 million for the three months ended June 30, 2026 and 2025, respectively. The increase of $6.8 million between the comparative three month periods was primarily due to an increase of $4.3 million in personnel-related costs due to an increase in headcount and higher non-cash stock-based compensation expense, an increase of $3.2 million related to progression of our clinical development of the MZE829 program and an increase of $0.9 million related to our discovery research and other programs, partially offset by a $1.4 million decrease related to the MZE782 program primarily due to higher costs incurred in 2025 for the Phase 1 clinical trial in healthy adult volunteers that completed in 2025.

Research and development expenses were $69.1 million and $55.7 million for the six months ended June 30, 2026 and 2025, respectively. The increase of $13.4 million between the comparative six month periods was primarily due to an increase of $7.9 million in personnel-related costs due to an increase in headcount and higher non-cash stock-based compensation expense, an increase of $5.7 million related to progression of our clinical development of the MZE829 program and an increase of $0.9 million related to our discovery research and other programs, partially offset by a $0.5 million decrease related to the MZE782 program primarily due to higher costs incurred in 2025 for the Phase 1 clinical trial in healthy adult volunteers that completed in 2025 and a $0.6 million decrease in lab supplies and other costs.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
		(in thousands)			(in thousands)	
Direct external research and development expenses by program:						
MZE829	$ 8,444	$ 5,199	$ 3,245	$ 15,540	$ 9,823	$ 5,717
MZE782	3,177	4,582	(1,405)	8,471	8,948	(477)
Discovery research and other programs	3,596	2,742	854	6,641	5,752	889
Internal research and development expenses:						
Personnel-related	14,875	10,609	4,266	28,866	20,953	7,913
Facilities, lab supplies and other	4,848	4,976	(128)	9,570	10,212	(642)
Total research and development expenses	$ 34,940	$ 28,108	$ 6,832	$ 69,088	$ 55,688	$ 13,400

General and administrative expenses

General and administrative expenses were $13.1 million and $8.4 million for the three months ended June 30, 2026 and 2025, respectively. The increase of $4.7 million between the comparative three month periods was primarily due to an increase in personnel-related costs due to an increase in headcount and higher non-cash stock-based compensation expense.

General and administrative expenses were $25.5 million and $16.2 million for the six months ended June 30, 2026 and 2025, respectively. The increase of $9.3 million between the comparative six month periods was primarily due to an increase of $8.0 million in personnel-related costs due to an increase in headcount and higher non-cash stock-based compensation expense and an increase of $0.7 million for professional services.

Total other income, net

Total other income, net was $3.3 million and $2.8 million for the three months ended June 30, 2026 and 2025, respectively. The increase of $0.5 million between the comparative three months periods primarily reflects an increase in interest income as a result of higher cash, cash equivalent, and marketable securities balances held during the three months ended June 30, 2026 resulting from the net proceeds received from the underwritten registered offering completed in April 2026 and proceeds from the initial term loan funded under the Hercules Loan Agreement in February 2026, partially offset by interest expense recognized on the Hercules Loan Agreement.

Total other income, net was $5.7 million and $5.4 million for the six months ended June 30, 2026 and 2025, respectively. The increase of $0.3 million between the comparative six months periods primarily reflects an increase in interest income as a result of higher cash, cash equivalent, and marketable securities balances held during the six months ended June 30, 2026 resulting from the net proceeds received from the underwritten registered offering completed in April 2026 and proceeds from the initial term loan funded under the Hercules Loan Agreement in February 2026, partially offset by interest expense recognized on the Hercules Loan Agreement.

Liquidity and capital resources

Liquidity

Since our inception, we have not generated any revenue from product sales and we do not expect to generate any revenue from commercial sales for the foreseeable future, if at all. We have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. To date, we have financed our operations primarily through sales of our equity and convertible promissory notes, debt financing, as well as one-time, nonrefundable upfront payments we received pursuant to the license agreements we entered into with several biotechnology companies in 2024, including the exclusive license agreement with Shionogi. As of June 30, 2026, we had cash, cash equivalents and marketable securities of $494.9 million and an accumulated deficit of $558.5 million.

In February 2026, we entered into an Open Market Sale Agreement with Jefferies LLC, serving as sales agent, with respect to an at-the-market offering program pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $200.0 million, or the 2026 Sale Agreement, in such quantities and on such minimum price terms as we set from time to time through our sales agent. We have agreed to pay our sales agent an aggregate commission equal to up to 3.0% of the gross proceeds of the sales under the agreement. To date, no sales of common stock have occurred under the 2026 Sale Agreement.

Additionally, in February 2026, we entered into the Hercules Loan Agreement which provides for a senior secured term loan facility in an aggregate principal amount of up to $200.0 million. An initial term loan of $40.0 million was funded under the Hercules Loan Agreement and an aggregate of $160.0 million in additional term loans commitments will be available to us through February 2031, so long as we satisfy certain conditions precedent. The final tranche of $50.0 million is subject to approval by the lenders' investment committee. The facility has a maturity date of February 1, 2031, and may be prepaid at any time, subject to prepayment premiums. This senior secured term facility will accrue interest at an annual rate determined by reference to the Prime Rate as reported in the Wall Street Journal, with interest rate floors that range from 7.95% to 9.25% depending on the tranche. The Hercules Term Loan Facility provides for payment of interest only until (a) 48 months after the Closing Date or (b) if certain performance and financing milestones are satisfied, 60 months after the Closing Date. Accrued interest on the Term Loans is payable on the first business day of each month. In connection with the Hercules Loan Agreement, we terminated an existing loan and security agreement with another bank that provided us with a line of credit of up to $50.0 million. We did not draw down any funds from this terminated debt facility. See Note 10, Loan and security agreements, of this Quarterly Report on Form 10-Q for further discussion of the Hercules Loan Agreement.

In April 2026, we completed an underwritten registered offering pursuant to which we issued and sold an aggregate of 5,540,000 shares of our common stock at a purchase price of $23.50 per share and pre-funded warrants to purchase up to an aggregate of 850,000 shares of our common stock, or the 2026 Pre-Funded Warrants, at a purchase price of $23.499 per pre-funded warrant, which represents the per share offering price for the shares of common stock less a $0.001 per share exercise price for each pre-funded warrant, resulting in net proceeds of approximately $144.6 million, after deducting underwriting discounts and commissions and estimated offering expenses, or the Underwritten Registered Offering. See Note 6, Capital structure, of this Quarterly Report on Form 10-Q for further discussion of the Underwritten Registered Offering.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least one year from the date of this Quarterly Report on Form 10-Q. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

Funding requirements

We do not expect to generate any meaningful future revenue unless and until we obtain regulatory approval and commercialize any of our current or future therapeutic candidates, including MZE829 and MZE782, or receive additional potential revenue from the achievement of milestones and royalties under our existing license agreements or potential additional partnerships, and we do not know when, or if at all, that will occur. We will continue to require additional capital to develop our therapeutic candidates and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses related to our programs, and to a lesser extent, general and administrative expenses. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to develop MZE829, MZE782 and our other discovery and preclinical programs, seek to broaden the pipeline of our product candidates and further develop our Compass platform. In addition, we expect to incur additional costs associated with operating as a public company.

We may seek to raise capital through equity or debt financings, license and collaboration agreements or other arrangements, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the costs associated with the type, scope, progress and results of research and discovery, preclinical development, laboratory testing and clinical trials for our current or future therapeutic candidates, including MZE829 and MZE782;
- the extent to which we develop, in-license or acquire other pipeline therapeutic candidates or technologies;
- the number and development requirements of other therapeutic candidates that we may pursue, and other indications for our current therapeutic candidates that we may pursue;
- the costs related to entering into partnerships or other arrangements with third parties;
- the costs, timing and outcome of obtaining regulatory approvals of our current or future therapeutic candidates we may pursue;
- the costs and fees associated with the discovery, acquisition or in-license of our products or technologies, including to maintain and expand our Compass platform;
- the scope and costs of making arrangements with third-party manufacturers for preclinical, clinical and commercial supplies of our current or future therapeutic candidates;
- the scope and costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future therapeutic candidates;
- the cost associated with commercializing any approved therapeutic candidates, including establishing sales, marketing and distribution capabilities;
- the cost associated with completing any post-marketing studies or trials required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities;
- the revenue, if any, received from commercial sales of our current or future therapeutic candidates, if any are approved;
- the costs associated with addressing any potential interruptions or delays resulting from factors related to overall global affairs, such as conflicts overseas;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- our ability to establish and maintain collaboration arrangements on favorable terms, if at all and the timing and amount of any milestone, royalty or other payments we are required to make or are eligible to receive under such collaborations, if any.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any debt financing that we raise or additional equity that we issue may contain terms that are not favorable to us or our stockholders.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our proprietary technology, future revenue streams, research programs or therapeutic candidates, including granting licenses to our proprietary technologies, on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

We have an operating lease for a facility in South San Francisco, California with office and laboratory space, which serves as our corporate headquarters. The lease terminates in November 2030 and provides for one option to extend the lease term for an additional period of eight years.

We have entered into consortium agreements with the University of Helsinki to access genomic information from patient samples and genetic and paired clinical data. As of June 30, 2026, we are obligated to pay $3.5 million under these agreements through the year ended December 31, 2027.

We are obligated to make principal loan payments, interest payments and pay an end of term charge under the Hercules Loan Agreement. See Note 10, Loan and security agreements, of this Quarterly Report on Form 10-Q for further discussion of the Hercules Loan Agreement.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical trials, non-clinical trials and testing, and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice.

Cash flows

Comparisons of the six months ended June 30, 2026 and 2025

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for the periods presented below:

	Six Months Ended June 30,		
	2026	2025	Change
	(in thousands)		
Net cash used in operating activities	$ (54,166)	$ (59,568)	$ 5,402
Net cash used in investing activities	(122,231)	(692)	(121,539)
Net cash provided by financing activities	189,793	127,990	61,803
Net increase in cash, cash equivalents and restricted cash	$ 13,396	$ 67,730	$ (54,334)

Net cash used in operating activities

Net cash used in operating activities was $54.2 million and $59.6 million for the six months ended June 30, 2026 and 2025, respectively. The net cash used in operating activities for the six months ended June 30, 2026 was primarily due to our net loss of $68.9 million combined with a net change in our operating assets and liabilities of $4.6 million, offset by $19.3 million in non-cash charges such as depreciation, stock-based compensation, lease expense and amortization of debt discount and debt issuance costs. The net cash used in operating activities for the six months ended June 30, 2025 was primarily due to our net loss of $66.5 million combined with a net change in our operating assets and liabilities of $2.5 million, offset by $9.4 million in non-cash charges such as depreciation, stock-based compensation and lease expense.

Net cash used in investing activities

Net cash used in investing activities was $122.2 million and $0.7 million for the six months ended June 30, 2026 and 2025. The net cash used in investing activities for the six months ended June 30, 2026 consisted of purchases of marketable securities of $186.0 million and purchases of property and equipment of $0.2 million, offset by maturities of marketable securities of $64.0 million. Net cash used in investing activities for the six months ended June 30, 2025 consisted of purchases of property and equipment of $0.7 million.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2026 was $189.8 million, which consisted of net proceeds of approximately $144.6 million from the issuance of common stock and 2026 Pre-Funded Warrants pursuant to the Underwritten Registered Offering, net proceeds of $38.5 million from the Hercules Loan Agreement, $5.8 million from the exercise of stock option awards and $1.0 million from the issuance of common stock under the 2025 Employee Stock Purchase Plan. For the six months ended June 30, 2025, net cash provided by financing activities was $128.0 million, which consisted of net proceeds of approximately $127.8 million from the issuance of common stock pursuant to our initial public offering, $0.6 million from the issuance of common stock under the 2025 Employee Stock Purchase Plan and $0.1 million from the exercise of stock option awards, offset by the payment of $0.5 million for the success fee under the loan and security agreement with Banc of California.

Critical accounting policies, significant judgments and use of estimates

Our significant accounting policies are described in detail in the notes to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q. We described the accounting policies that we believe involve a significant level of estimation and uncertainty, which could have a material impact on our financial condition or results of operations and are therefore deemed critical accounting policies, in our "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March, 25, 2026. There have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2026.

Our condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The preparation of these condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Emerging growth company status

We are an emerging growth company, or EGC. The Jumpstart Our Business Startups Act of 2012, or the JOBS Act permits companies with EGC status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if, as an EGC, we intend to rely on such exemptions, 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) of the Sarbanes-Oxley Act of 2002, as amended; (ii) provide all of the compensation disclosure that may be required of non-EGCs under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis); and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

We will remain an EGC under the JOBS Act until the earliest of (i) the last date of our fiscal year in which we have total annual gross revenue of at least $1.235 billion, (ii) the date we qualify as a "large accelerated filer," as defined under Rule 12b-2 of the Exchange Act, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years, or (iv) the last day of our first fiscal year following the fifth anniversary of the closing of our initial public offering.

Recent accounting pronouncements

See Note 2, Summary of significant accounting policies, to our unaudited condensed financial statements included in Part 1, Item 1, "Financial Statements (Unaudited)," of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks that may result from changes in interest rates and foreign currency exchange rates.

Interest Rate Risk

Investments in marketable securities

As of June 30, 2026 and December 31, 2025, we had cash, cash equivalents and marketable securities of $494.9 million and $360.0 million, respectively. This consisted of interest-bearing money market accounts and investments in U.S. government securities, commercial paper, and corporate debt securities, which create an exposure to interest rate risk. Our future interest income may fall short of expectations due to changes in market conditions and in interest rates and such changes in interest rates may affect the fair value of the marketable securities held in our portfolio and cause unrealized gains or losses. Such gains or losses would not be realized unless the investments are sold. A hypothetical one percent increase in interest rates as of June 30, 2026 and December 31, 2025 would not have resulted in a material effect on the fair market value of our cash, cash equivalents and marketable securities.

Long-term debt

As of June 30, 2026 we had an outstanding term loan with a carrying value of $39.0 million bearing interest at a rate equal to the greater of (i) 7.95% or (ii) the prime rate plus 0.95%. A hypothetical one percent increase in the prime rate as of June 30, 2026 would not have resulted in a material effect on the fair market value of our debt. In addition, a hypothetical one percent increase in the prime rate as of June 30, 2026 would not result in a material impact to our income for the year ending December 31, 2026. We did not have any outstanding debt as of December 31, 2025.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the euro and British pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of preclinical, clinical and manufacturing activities. We do not hedge our foreign currency exchange rate risk, however, we may do so in the future. As of June 30, 2026 and December 31, 2025, we had no material accounts payable or receivable denominated in foreign currencies, and a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have a material impact on our condensed financial statements.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2026, our management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2026, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm.

Item 1A. Risk Factors

Risk Factors

Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. We cannot assure you that any of the events discussed below will not occur. You should carefully consider the following risk factors, together with the information contained herein and in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission, or SEC, on March 25, 2026, including our financial statements and the related notes, and our other filings with the SEC, before deciding whether to invest in our common stock. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. These disclosures reflect the management's beliefs and opinions as to factors that could materially and adversely affect the Company and its securities in the future. References to past events are provided by way of example only and are not intended to be a complete listing of such events or a representation as to whether or not such factors or similar events have occurred in the past or their likelihood of occurring in the future. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

Risks related to our limited operating history, financial position and need for capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. Since our inception, we have incurred significant operating losses and have not generated any product revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history. Our lead programs are still in early clinical development, and we are subject to the risks of failure inherent in the development of therapeutic candidates based on novel technologies. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Furthermore, we do not expect to generate any product revenue from commercial sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of clinical trials, preclinical studies, research and development, and the regulatory approval process of our therapeutic candidates. For the three and six months ended June 30, 2026, we incurred a net loss of $44.7 million and $68.9 million, respectively. For the three and six months ended June 30, 2025, we incurred a net loss of $33.7 million and $66.5 million, respectively. As of June 30, 2026, we had an accumulated deficit of $558.5 million. We expect to continue to incur significant research and development and other expenses related to our ongoing operations.

Since our inception, we have focused substantially all of our efforts and financial resources on research and development activities for our programs and on establishing arrangements and collaborations with third parties for the development of our therapeutic candidates. To date, we have not generated any product revenue from product sales and have financed our operations primarily through sales of our equity and convertible promissory notes, debt financing, as well as one-time, nonrefundable, upfront licensing payments.

Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with the ongoing clinical trials for our lead programs, MZE829 and MZE782, further development of our Maze Compass platform, or our Compass platform, planned preclinical studies, IND filings and clinical trials for future therapeutic candidates. We will also incur substantial additional expenses as we seek to expand our intellectual property portfolio, including through potential in-licensing opportunities, and hire additional personnel as we scale up our operations. We expect to continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue apart from upfront licensing payments, and we do not know when, or if, we will generate any sales, milestone, or royalty revenue. We do not expect to generate additional significant revenue from licensing arrangements in the near term. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, our therapeutic candidates.

To become and remain profitable, we must succeed in designing, developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including therapeutic candidate selection, preclinical testing and clinical trials of our therapeutic candidates, continuing to discover and develop additional therapeutic candidates, establishing arrangements with third parties for the manufacture of preclinical and clinical supplies, obtaining regulatory approval for any therapeutic candidates that successfully complete clinical trials, manufacturing, marketing and selling any products for which we may obtain marketing approval and obtaining coverage and adequate reimbursement from government and third-party payors for any such products. We are only in the preliminary stages of development and clinical trials, and we may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability or meet outside expectations for our profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we decide to or are required by the U.S. Food and Drug Administration, or FDA, or regulatory authorities in other jurisdictions to perform preclinical studies or clinical trials in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating clinical trials or preclinical studies for, or in the development of any of our therapeutic candidates, our expenses could increase materially and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting clinical trials and preclinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance our developmental programs, advance our current clinical trial and preclinical studies, commence additional clinical trials and preclinical studies and expand the breadth of our Compass platform. In addition, even if we obtain marketing approval for any of our therapeutic candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional capital in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our clinical and preclinical development, research and development programs, our commercialization plans or other operations.

As of June 30, 2026, our cash, cash equivalents and marketable securities were $494.9 million. Based on our current operating plan, we believe our existing cash, cash equivalents and marketable securities as of June 30, 2026 will enable us to fund our operating expenses and capital expenditure requirements for at least one year from the date of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including, but not limited to:

- the costs associated with the type, scope, progress and results of research and discovery, preclinical development, laboratory testing and clinical trials for our current or future therapeutic candidates, including MZE829 and MZE782;
- the extent to which we develop, in-license or acquire other pipeline therapeutic candidates or technologies;

- the number and development requirements of other therapeutic candidates that we may pursue, and other indications for our current therapeutic candidates that we may pursue;
- the costs related to entering into partnerships or other arrangements with third parties;
- the costs, timing and outcome of obtaining regulatory approvals of our current or future therapeutic candidates we may pursue;
- the costs and fees associated with the discovery, acquisition or in-license of our products or technologies, including to maintain and expand our Compass platform;
- the scope and costs of making arrangements with third-party manufacturers for preclinical, clinical and commercial supplies of our current or future therapeutic candidates;
- the scope and costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future therapeutic candidates;
- the costs associated with commercializing any approved therapeutic candidates, including establishing sales, marketing and distribution capabilities;
- the costs associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of our current or future therapeutic candidates, if any are approved;
- the costs associated with addressing any potential interruptions or delays resulting from factors related to overall global affairs, such as conflicts overseas;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- our ability to establish and maintain collaboration arrangements on favorable terms, if at all and the timing and amount of any milestone, royalty or other payments we are required to make or are eligible to receive under such collaborations, if any.

We will require additional capital for our research and development programs. Our ability to raise additional funds will be dependent on financial, economic and market conditions, geopolitical issues and other factors, over which we may have limited or no control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate our research and development activities of all or part of our research programs or therapeutic candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future therapeutic candidates, if approved. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Raising additional capital may cause dilution to our stockholders, cause the price of our common stock to decline, restrict our operations or require us to relinquish rights to our technologies or therapeutic candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We have an effective Form S-3ASR automatic shelf registration statement, or the "Shelf Registration," on file with the Securities and Exchange Commission, or SEC, which allows us to sell any combination of common stock, preferred stock, debt securities, warrants, subscription rights, and/or units consisting of one or more of the foregoing in one or more offerings.

We have also entered into an Open Market Sale Agreement with Jefferies LLC, serving as our sales agent, with respect to an at-the-market offering program pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $200.0 million, or the 2026 Sale Agreement, in such quantities and on such minimum price terms as we set from time to time through our sales agent. To date, no sales have occurred under the 2026 Sale Agreement.

In April 2026, we completed an underwritten registered offering pursuant to which we issued and sold an aggregate of 5,540,000 shares of our common stock at a purchase price of $23.50 per share and pre-funded warrants to purchase up to an aggregate of 850,000 shares of our common stock at a purchase price of $23.499 per pre-funded warrant, which represents the per share offering price for the shares of common stock less a $0.001 per share exercise price for each pre-funded warrant, resulting in net proceeds of approximately $144.6 million, after deducting underwriting discounts and commissions and offering expenses.

The issuance of additional shares of our common stock pursuant to the Shelf Registration or the 2026 Sale Agreement, or issuances of securities convertible into or exercisable for our common stock or other equity-linked securities, including preferred stock, warrants, debt securities or units, would dilute the ownership interest of our existing stockholders. Further, any such sales, or the anticipation of such sales, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional securities. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic 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 therapeutic candidates, including granting licenses to our technologies, on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Our loan and security agreement provides our lender with a first priority lien against substantially all of our assets, except for intellectual property, and contains restrictive and financial covenants that may limit our operating flexibility.

On February 4, 2026, we entered into a loan and security agreement, or the Hercules Loan Agreement, with certain lenders and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the lenders party thereto, which provides for a senior secured term loan facility, or the Hercules Term Loan Facility, in an aggregate principal amount of up to $200.0 million. An initial term loan of $40.0 million was funded under the Hercules Loan Agreement and the Hercules Term Loan Facility includes up to six additional term loan tranches providing up to an aggregate $160.0 million in additional loan commitments through February 2031, so long as we satisfy certain conditions precedent. The final tranche of $50.0 million is subject to approval by the lenders' investment committee. The facility has a maturity date of February 1, 2031, and may be prepaid at any time, subject to prepayment premiums. This senior secured term facility will accrue interest at an annual rate determined by reference to the Prime Rate as reported in the Wall Street Journal, with interest rate floors that range from 7.95% to 9.25% depending on the tranche. Accrued interest is payable on the first business day of each month until (a) February 2030 or (b) if certain performance and financing milestones are satisfied, the maturity date. The Federal Reserve has raised, and may in the future further raise, interest rates to combat the effects of recent high inflation. An increase in the prime rate resulting in interest rates above the set minimum rate would increase our debt service obligations, which could have a negative impact on our cash flow, financial position or operating results, or result in increased borrowing costs in the future.

All of our obligations under the Hercules Loan Agreement are secured by a first lien perfected security interest on substantially all of our existing assets and after-acquired assets, except for intellectual property, subject to customary exceptions.

The Hercules Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require us to undertake various reporting and notice requirements and an obligation to maintain in force certain rights, approvals and assets. The negative covenants restrict or limit our ability to, among other things and subject to certain exceptions contained in the Hercules Loan Agreement, incur new indebtedness, create liens on assets, engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities, and to make Investments (as defined in the Hercules Loan Agreement) or distributions, or redemptions, in each case subject to customary exceptions. The negative covenants also restrict our ability to change our fiscal year, repay certain other indebtedness, engage in certain affiliate transactions, or enter into, amend or terminate any other agreement that has the impact of restricting our ability to make loan repayments under the Hercules Loan Agreement. In addition, unless either (i) our market capitalization is greater than or equal to $450.0 million and an aggregate of no more than $85.0 million in principal amount is outstanding under the term loans or (ii) our market capitalization is greater than or equal to $750.0 million, we must at all other times maintain unrestricted cash and cash equivalents of at least 50% of the outstanding loan amount, decreasing to 40% and 35% upon satisfaction of certain performance and financing milestones. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default under the Hercules Loan Agreement or under any future financing agreements that we may enter into, which would give our lenders the right to terminate their commitments to provide loans and to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. Conforming to such restrictive and financial covenants under the Hercules Loan Agreement may limit our operating flexibility and we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market therapeutic candidates that we would otherwise prefer to develop and market ourselves.

The Hercules Loan Agreement also contains certain customary Events of Default (as defined in the Hercules Loan Agreement). The occurrence of an Event of Default could result in, among other things, the declaration that all outstanding principal and interest under the Hercules Term Loan Facility are immediately due and payable in whole or in part. See Note 10, Loan and security agreement, in Part I, Item 1 of this Quarterly Report on Form 10-Q for further discussion of the Hercules Loan Agreement.

Risks related to discovery and development of our therapeutic candidates

We are early in our development efforts and highly dependent on the success of our lead programs. If we are unable to commercialize our therapeutic candidates or experience significant delays in doing so, our business will be materially harmed.

Our therapeutic candidates are in early stages of development. We do not have any products that are approved for sale in any jurisdiction. We initiated a Phase 2 trial of MZE829, our most advanced lead program, in November 2024, dosed our first patient in February 2025 and reported positive topline clinical proof of concept data in March 2026. We plan to initiate a pivotal trial of MZE829 in the first half of 2027, subject to regulatory feedback. We initiated a Phase 1 clinical trial of our second lead program, MZE782, in September 2024 and announced initial clinical data in healthy adult volunteers in September 2025. In August 2026, we announced that the Phase 2 proof-of-concept trial of MZE782 in patients with phenylketonuria, or PKU, has initiated and we anticipate reporting topline data from this trial in 2027. We plan to initiate a Phase 2 proof-of-concept trial of MZE782 in patients with CKD in the first half of 2027. Our other programs are at an early research stage, with no therapeutic candidates identified. Our research programs may not result in viable therapeutic candidates for some time, if ever, and our therapeutic candidates in development may not achieve success in our current or any future clinical trials, or obtain regulatory approval.

Our ability to generate product revenues, which may not occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our therapeutic candidates. The success of our therapeutic candidates will depend on several factors, including, but not limited to:

- timely and successful completion of, and timely enrollment of patients in, clinical trials with favorable results;
- submission of new drug applications, or NDAs, or other regulatory applications, and receipt and related terms of regulatory approvals from applicable regulatory authorities, including the completion of any required post-marketing studies or trials and available funding to perform any post-marketing commitments;
- raising additional funds necessary to complete clinical development of and commercialize our therapeutic candidates;
- timely and successful completion of preclinical studies with favorable results;
- submission of INDs or other regulatory applications, and authorizations to initiate clinical trials from the FDA and foreign regulatory agencies;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our therapeutic candidates to the satisfaction of the FDA and foreign regulatory authorities;

- obtaining, maintaining, defending and enforcing patent, trade secret and other intellectual property and proprietary protection and regulatory exclusivity for our therapeutic candidates;
- making arrangements with third-party suppliers and manufacturers for preclinical, clinical and commercial supplies of our therapeutic candidates;
- developing and implementing marketing and reimbursement strategies, as well as adequate demand forecasts for supply and sales planning;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others in a market where promotional sales approaches are rapidly moving to digital platforms;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including those that have not yet entered the market;
- obtaining and maintaining third-party payor coverage and adequate reimbursement;
- obtaining appropriate support from patient advocacy organizations;
- addressing any delays in our clinical trials, or in the manufacture or distribution of our therapeutic candidates, if approved, resulting from any major natural disasters, health pandemics, economic conditions or significant political events; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our therapeutic candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. Even if we do obtain regulatory approval, it is possible that one or more of these factors could cause significant delays or an inability to successfully commercialize our therapeutic candidates, which would materially harm our business.

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 therapeutic candidates, or may negatively impact the perceptions of value or risk of our technologies.

Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our therapeutic candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.

We have limited experience designing and implementing clinical trials. We initiated a Phase 2 trial of MZE829, our most advanced lead program, in November 2024, dosed our first patient in February 2025 and reported positive topline clinical proof of concept data in March 2026. We plan to initiate a pivotal trial of MZE829 in the first half of 2027, subject to regulatory feedback. We initiated a Phase 1 clinical trial of MZE782 in September 2024 and announced initial clinical data in healthy adult volunteers in September 2025. In August 2026, we announced that the Phase 2 proof-of-concept trial of MZE782 in patients with PKU has initiated and we anticipate reporting topline data from this trial in 2027. We plan to initiate a Phase 2 proof-of-concept trial of MZE782 in patients with CKD in the first half of 2027. Failure to design any one of our clinical trials adequately, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or use the clinical trial's results to support an application for regulatory approval, as well as lead to increased or unexpected costs.

Our programs are in the early stages of development, and the risk of failure is high. Our programs may fail to identify potential therapeutic candidates for clinical development for a number of reasons. We are unable to predict when or if our programs will lead to therapeutic candidates or when or if our therapeutic candidates will prove effective and safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any of our therapeutic candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our therapeutic candidates in humans. Our potential therapeutic candidates may be shown to have harmful side effects in animal model studies, may not show promising signals of therapeutic effect in such experiments or studies, or may have other characteristics that may make the therapeutic candidates impractical to manufacture, unmarketable, or unlikely to receive marketing approval.

We are currently focused on advancing the development of our lead programs, MZE829 and MZE782; however, even with significant investment of time and funding to advance these therapeutic candidates, we cannot guarantee that our clinical and preclinical development efforts will be successful. The start or end of a clinical trial may be delayed or halted due to delays in or failure to obtain regulatory approval to commence the trial, delays in or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, or clinical trial sites, delays in or failure to obtain Institutional Review Board, or IRB, approval at each site, changing regulatory requirements, manufacturing challenges, clinical sites or CROs deviating from the trial protocol or failing to comply with regulatory requirements or meet contractual obligations, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative therapeutic or required prior therapy, clinical outcomes, failure of patients to complete the trial or return for post-treatment follow-up, or financial constraints. Delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times, requirements to manufacture additional drug supply, or termination of a clinical trial.

Clinical trials of a new therapeutic candidate require the enrollment of a sufficient number of patients, which may include patients who are suffering from the disease the therapeutic candidate is intended to treat and who meet other eligibility criteria, which may require genetic testing of prospective patients. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, the age and condition of the patients, the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites, and the availability of effective treatments or competing academic and other sponsored clinical trials for the relevant disease.

A therapeutic candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for therapeutic candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care, and other variables. Although our Compass platform was designed to increase the probability of developing new medicines, it may still result in high failure rates equivalent to historical norms. We will have to conduct additional trials in our proposed indications to support any future regulatory submissions. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether our clinical trials will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use that is sufficient to receive regulatory approval or market our therapeutic candidates. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory agencies for supporting a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our therapeutic candidates.

We, the FDA, an IRB, an independent ethics committee, or EC, or other applicable regulatory authorities may suspend clinical trials of a therapeutic candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. Similarly, an IRB or EC may suspend a clinical trial at a particular trial site. We may not have the financial resources to continue development of, or to enter into collaborations for, a therapeutic candidate if we experience any problems or other unforeseen events delaying or preventing clinical development or regulatory approval of, or our ability to commercialize, therapeutic candidates, including:

- negative or inconclusive results from our clinical trials, or the clinical trials of others for therapeutic candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using therapeutics similar to our therapeutic candidates;
- serious drug-related side effects experienced in the past by individuals using therapeutics similar to our therapeutic candidates;
- delays in submitting IND applications, clinical trial applications or comparable foreign applications, or delays or failure in obtaining the necessary approvals from regulators or IRBs to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities, such as the European Medicines Agency, or EMA, regarding the scope or design of our clinical trials;
- delays or difficulty in enrolling research subjects in clinical trials, for a variety of reasons including, but not limited to, change in priorities for clinical trial sites, the clinical trials of other therapeutic candidates or approval of a competitor’s product for the same indication;
- high drop-out rates of research subjects;

- inadequate supply or quality of therapeutic candidate or therapeutic candidate components, or materials or other supplies necessary for the conduct of our clinical trials, including those owned, manufactured, or provided by companies other than ours;
- greater than anticipated clinical trial costs, including the cost of any approved drugs used in combination with our therapeutic candidates;
- poor effectiveness of our therapeutic candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

If we are impacted by one or more of these factors and are unable to remediate the issue in a timely manner or at all, then we could experience significant delays or an inability to successfully obtain regulatory approvals for our therapeutic candidates. Without regulatory approval, we will be unable to commercialize our therapeutic candidates, which would materially harm our business and potentially make it impossible to continue our operations.

Results of preclinical studies or early-stage clinical trials of any therapeutic candidates may not be predictive of the results of future preclinical studies or clinical trials.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later preclinical studies or clinical trials or of clinical trials of the same therapeutic candidates in other indications, and interim or preliminary results of a clinical trial do not necessarily predict final results. For example, even if successful, the results of our preclinical studies or early clinical trials for our lead programs may not be predictive of the results of outcomes in subsequent clinical trials. Later-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design.

If we encounter delays or difficulties enrolling patients in our clinical trials and/or retaining patients in 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 external reasons beyond our control, including supply chain disruptions, staffing shortages and other business and economic disruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, as well as other disruptions resulting from the impact of public health factors, including pandemics or other health crises, business disruptions of our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely. Our therapeutic candidates are developed using a precision medicine approach intended to identify specific targets amenable to therapeutic intervention in kidney and metabolic diseases. As a result, the potential population of patients eligible for enrollment in our clinical trials may be smaller than the population eligible for enrollment in trials targeting the entire population with the disease, and it may be difficult to identify and enroll adequate numbers of patients in our trials. For example, our therapeutic candidate MZE829 is targeted to treat kidney disease associated with genetic variations in the APOL1 gene, which are most prevalent in people of West African ancestry, including many who identify as Black, African American, Afro-Caribbean and Latina/Latino, which narrows the patient population eligible for enrollment in these trials.

In addition, the eligibility criteria of our clinical trials will further limit the pool of available trial participants. For our therapeutic candidate MZE829, we depend on and expect to perform genetic screening in order to identify candidates with the applicable genetic variations for our clinical trials. As we expect future therapeutic candidates to also target specific subgroups of common conditions, as identified through our Compass platform, it is likely that future therapeutic candidates will also require identification of patients with the applicable genotype or other specific disease biomarkers, which will require genetic and/or specific clinical tests for screening and further costs and timing delays in identifying patients eligible for our clinical trials. Such screening could involve more time consuming, costly and invasive procedures than patients may be willing to accept. If patients are not willing to undergo screening, or any other eligibility criteria we have for our clinical trials, it would lead to greater costs and/or timing delays for us in order to identify eligible and the necessary patients for our clinical trials. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of eligible patients who remain in the trial until completion of treatment and adequate follow-up. In general, the enrollment and retention of patients depends on many factors, including, but not limited to:

- the patient eligibility criteria defined in the protocol;
- the perceived risks and benefits of the therapeutic candidate being studied;
- 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;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to obtain and maintain patient consent;
- external factors such as geopolitical events, infectious disease outbreaks and public health crises;
- geopolitical events in countries where we have or seek to have clinical trial sites;
- reporting of the preliminary results of any of our clinical trials; and
- potential approval and commercial availability of a competitor's product for the same indication.

In addition, our clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as our therapeutic candidates, and this competition will reduce the number and types of patients available to or retained by us because patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one or more of our competitors. Other biopharmaceutical companies are currently conducting clinical trials, and may in the future conduct clinical trials, that compete for the same patient population as us. Since the number of qualified clinical investigation sites is limited, and often associated with a small number of academic centers, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Our therapeutic candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

If serious adverse events or undesirable side effects arise, we could be required to suspend, delay, or halt our clinical trials. Additionally, serious adverse events or undesirable side effects could cause regulatory authorities to deny approval or require us to limit development of that therapeutic candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Side effects that are observed during trials, whether treatment related or not, could also affect patient recruitment for future trials or the ability of enrolled patients to complete the trial or result in potential product liability claims. Many compounds that initially show promise in clinical or preclinical testing are later found to cause undesirable or unexpected side effects that prevent further development of the compound.

Further, if serious adverse events or undesirable side effects are identified during development or after approval and are determined to be attributed to any of our therapeutic candidates, we may be required to develop Risk Evaluation and Mitigation Strategies, or REMS, to ensure that the benefits of treatment with such therapeutic candidate outweigh the risks for each potential patient. A REMS may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and other processes that would make our therapeutic candidate more restricted or costly to distribute to patients.

Our two lead programs are intended to treat CKD, which is a progressive condition associated with severe and often life-threatening co-morbidities. Clinical trials that involve patients with significant co-morbidities are associated with increased risks as such participants may be particularly susceptible to safety and toxicity risks. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as safety and toxicity monitoring may be complicated and difficult to manage, which could result in patient death or other significant issues. Additionally, it can be difficult to determine if the serious adverse or unexpected side effects were caused by our therapeutic candidate or some other factor, especially in subjects who may suffer from other medical conditions and take other medications.

Any of these occurrences may materially harm our business, financial condition and prospects.

We may not be successful in applying our Compass platform to identify targets with therapeutic potential or to discover and develop safe, effective or commercially viable therapeutic candidates.

We use our Compass platform to identify and prioritize potential drug targets, to assess the likelihood that we can develop a therapeutic candidate that interacts with the applicable target to elicit the desired therapeutic effect, and to transition these insights efficiently into well-supported therapeutic candidates. We believe our use of our Compass platform, which identifies and prioritizes targets using statistical modeling, variant functionalization tools, and traditional and computational drug discovery technologies, augmented with machine learning and artificial intelligence, or AI, increases our likelihood of producing therapies that provide meaningful clinical benefit, but past success in identifying potential therapeutic candidates does not assure similar future success with our other programs. We may not succeed in applying our Compass platform to identify targets or promising therapeutic candidates in the future. We therefore cannot provide any assurance that we will be able to successfully identify additional therapeutic candidates or advance any of our programs or future therapeutic candidates into clinical development, nor can we provide any assurance whether the application of our Compass platform will result in the ultimate regulatory approval of any of our therapeutic candidates.

Efforts to identify, acquire or in-license, and then develop therapeutic candidates require substantial technical, financial and human resources, whether or not any therapeutic candidates are ultimately identified. We apply our Compass platform to discover potential genetic targets for which we may be able to develop precision therapeutic candidates. Our efforts may initially show promise in identifying potential targets linked to diseases or conditions, yet fail to yield therapeutic candidates for clinical development or regulatory approval for many reasons, including the following:

- the platform methodology used may not be successful in identifying potential therapeutic candidates;
- competitors may develop alternatives that render any therapeutic candidates we develop obsolete;
- any therapeutic candidates we develop may be covered by third parties' patents or other exclusive rights;
- a therapeutic candidate may be shown, in subsequent preclinical or clinical investigations, to have harmful side effects or characteristics that indicate it is unlikely to be effective, or otherwise would not meet applicable regulatory criteria;
- a therapeutic candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a therapeutic candidate may not be accepted as safe and/or effective by physicians, patients, the medical community or third-party payors.

Certain of the diseases we, or which our partners, seek to treat have low prevalence and/or have available therapies, and it may be difficult for us or our partners to identify patients with these diseases or face competition in the recruitment of these limited groups of patients, which may lead to difficulties in enrolling clinical trials.

Genetically defined diseases generally, and especially some of those which our out-licensed programs target, including Pompe disease, have low prevalence and incidence. This could pose obstacles to the timely recruitment, enrollment and retention of a sufficient number of eligible patients into our partners' trials or limit a therapeutic candidate's commercial potential, and thus the milestone payments and royalties we would receive for those licenses. Other companies have ongoing clinical trials for therapeutic candidates that treat the same indications as our wholly owned and our out-licensed therapeutic candidates, and patients who otherwise would be eligible for our or our partners' planned clinical trials instead may enroll in clinical trials of our competitors' therapeutic candidates. In addition, where there are currently available therapies or if our competitors' therapeutic candidates gain regulatory approval and become commercially available, patients may be reluctant to enroll in a clinical trial. As more companies begin to focus attention and resources on therapeutic candidates to treat the same indications as the ones we have out-licensed, our licensees may experience delays or be unable to successfully recruit and enroll a sufficient number of eligible patients in their clinical trials.

Our licensees' inability to enroll a sufficient number of patients with these diseases into their planned clinical trials would result in significant delays and could cause them to not initiate or abandon one or more clinical trials altogether, potentially depriving us of milestone payments and royalties potentially associated with these licenses.

We may experience delays in commencing and completing, or ultimately be unable to complete, the development and/or commercialization of our therapeutic candidates.

Before we can initiate clinical trials of a therapeutic candidate in any indication, we must submit the results of preclinical studies to the FDA or to comparable foreign authorities, along with other information, including information about the therapeutic candidate's chemistry, manufacturing and controls, and our proposed clinical trial protocol, as part of an IND or comparable foreign regulatory filings.

The FDA may require us to conduct additional preclinical studies for any therapeutic candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs.

Any delays in the commencement or completion of preclinical studies or clinical trials could significantly affect our development costs. We may experience numerous unforeseen events during, or as a result of, preclinical studies or clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our therapeutic candidates, including, but not limited to:

- regulators, IRBs or ECs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA may disagree as to the design or implementation of our clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable preclinical studies or clinical trial contracts or clinical trial protocols with prospective CROs and prospective trial sites;
- the cost of our preclinical studies and clinical trials may be greater than we anticipate, and we may lack adequate funding to continue preclinical studies and clinical trials;
- our third-party partners may fail to obtain regulatory approval of companion diagnostic tests on which we may rely, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for various reasons, including a finding by us or by a Data Monitoring Committee that the participants are being exposed to unacceptable health risks;
- our therapeutic candidates may produce negative or inconclusive results, or have undesirable side effects or other unexpected characteristics, and we may decide, or our investigators, regulators or IRBs/ECs may require us, to conduct additional preclinical studies or clinical trials, or delay, halt or abandon our development programs;

- our clinical trials may be negatively impacted or delayed by changes to clinical trial protocol;
- the supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- global health crises or geopolitical conflict may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials.

Delays, including delays caused by the above factors and other factors described in this "Risk Factors" section, can be costly and could negatively affect our ability to complete preclinical studies or clinical trials or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on or be completed on a timely basis, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons, including safety concerns and noncompliance with regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our therapeutic candidates.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates or allow our competitors to bring products to market before we do, which may impair our ability to successfully commercialize our therapeutic candidates and harm our business and results of operations.

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

Because we have limited financial and managerial resources, we focus on research programs and therapeutic candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions and spending on current and future research and development programs may not yield any commercially viable products or profitable market opportunities, which may adversely affect our business, financial condition, results of operations and prospects. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty collaborations or arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

If ethical and other concerns surrounding the use of genetic information become widespread, there may be limitations on our ability to access genetic information for our Compass platform.

One of the pillars of our Compass platform is our ability to access and aggregate numerous and varied genomic and phenotypic data collections, particularly those that pair genetic and clinical data. Genetic testing to provide this data has given rise to ethical questions and controversies regarding confidentiality and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulate the use of genetic data, including by limiting the compilation of genetic information or prohibiting testing for genetic predisposition to various conditions, particularly for those that have no known cure. Some of the major data sources of genetic and clinical data for our Compass platform derive from publicly funded and managed databases. One of our key objectives is to continue to augment our access to diverse sources of genetic information from multiple population groups. If our access to these additional sources of human genetic data becomes restricted, due to governmental limitations or otherwise, the capability of our Compass platform may be reduced, and we may be unable to continue to recognize the benefits of our Compass platform on our expected timeframe, or at all, which would have a negative effect on our business or financial condition.

Interim, topline and preliminary data from preclinical studies and clinical trials that we or our partners 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 or our partners may make public interim, topline or preliminary data from our or their preclinical studies and clinical trials that are based on a preliminary analysis of then-available data, of which, the results, related findings and conclusions are subject to change following a more comprehensive review of the data or accumulation of additional data. Interim, topline or preliminary data from clinical trials that we or our partners 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. Interim, preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, preliminary or topline data that were previously made public. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our reputation and business, financial condition, results of operations and prospects.

Further, regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, analyses or conclusions, 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 drug candidate, and our company in general. 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 of, and commercialize, any of our current or future therapeutic candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we do not achieve our projected development goals in the time frames we announce or expect, the development of our therapeutic candidates may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other therapeutic development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions, estimates, calculations, conclusions, or analyses. The actual timing of these milestones can vary dramatically compared to our assumptions and estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our therapeutics may be delayed or never achieved, which could harm our business, financial condition, results of operations and prospects and may cause our stock price to decline.

Risks related to our reliance on third parties

Our Compass platform relies on access to high quality data repositories with paired genetic and clinical data and loss of such access, or the inability to use such data, could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on non-exclusive access to third-party data sources of genetic and paired clinical data for our Compass platform, including, among others, the University of Helsinki, Queen Mary University, the UK Biobank, Biobank Japan and the Million Veteran Program, as well as specialized databases such as the Chronic Renal Insufficiency Cohort which is managed by the National Institute for Diabetic, Digestive and Kidney Diseases, and other genetic data sets we have acquired or may acquire access to in the future. Our ability to access data from these and similar sources is vital to all phases of our Compass platform, including target identification and variant functionalization.

For the most part, we do not control the quantity or type of data that is stored in genetic data repositories, and we may only have access to summary level or aggregate data. Some institutions only provide access to their data for limited purposes, or will require us to make results publicly available. We cannot guarantee that our access to any particular source of genetic or paired clinical data will be available in the future, or that the data that is available will meet the needs of our business strategy or our Compass platform.

We pay substantial membership fees to access certain genetic data repositories. Our memberships provide us with certain preferred access to non-public data, as well as some oversight of the biobanks through membership in the steering committees for these organizations. Most of the other members of these consortiums are larger and better resourced than we are. Any termination of our arrangements with these organizations would require us to rely more heavily on less well-developed resources or require us to invest in finding alternative, and potentially more costly, genetic data resources, if such resources are available at all, and could delay or impair our research and development efforts.

Furthermore, while any loss of access to these or similar genetic data repositories may not directly impact the development of our lead programs, we cannot predict the effects such loss could have on our preclinical and clinical studies and development efforts and our ability to discover and develop additional therapeutic candidates, or optimize our future clinical trials.

While we have not identified any licenses that are required to conduct our genomics work to date, we may in the future identify a third-party technology we need to license to expand or continue to operate our Compass platform. For example, certain aspects of our Compass platform make use of CRISPR Cas9 technology at the early research stages, and while the patent coverage of such technology remains uncertain, certain institutions that have rights in CRISPR Cas9 patents have sought and may in the future seek to obtain license fees from biotechnology companies like ours. If we were unable to license or otherwise obtain access to such technology on reasonable terms or at all, and we were required to cease operation of our Compass platform, it would have a material adverse effect on our business, results of operations, financial condition and prospects.

We have entered, and may in the future enter, into strategic collaborations, transactions and licensing partnerships for research, development or commercialization of our programs, including our first therapeutic candidate MZE001, and we may not be able to realize the full value of these partnerships or our partnered programs.

Our Compass platform has identified, and may identify in the future, genetic targets and therapeutic candidates outside of our core area of focus in kidney and metabolic diseases. Our business strategy includes seeking strategic collaborations to advance these targets. For example, in 2024, we granted exclusive licenses to advance two programs related to targets we were pursuing in amyotrophic lateral sclerosis, or ALS— ATXN2 and UNC13A—to other biotechnology companies, as well as an exclusive license with a pharmaceutical partner, Shionogi & Co., Ltd., or Shionogi, to advance our first clinical stage therapeutic candidate, MZE001.

We may face significant competition in seeking appropriate strategic partners, and negotiating partnership or collaboration terms that are favorable to us, and the negotiation process may be time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our programs and therapeutic candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our therapeutic candidates as having the requisite potential to obtain marketing approval. Certain kinds of strategic transactions, including exclusive licenses, may be subject to potential government review, including by antitrust agencies such as the U.S. Federal Trade Commission, or FTC, which can add substantially to the time and expense of completing a transaction. For example, in 2023, the FTC conducted an investigation of our proposed exclusive license of the MZE001 program to Genzyme Corporation, a subsidiary of Sanofi, and ultimately filed an action to enjoin the transaction based upon allegations that the Genzyme license would substantially lessen competition among pharmaceutical treatments for Pompe disease. If we are unable to license or collaborate on our programs, we may have to curtail the development of the therapeutic candidate for which we are seeking a partner, reduce or delay its development program or one or more of our other development programs, increase our expenditures and undertake development activities at our own expense, or accept terms that are for a lower value than we believe the asset is worth.

In our arrangements with third parties, we have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of our therapeutic candidates. Our ability to generate revenues from these arrangements will depend on our partners' abilities and efforts to successfully perform the functions assigned to them in these arrangements to meet regulatory and development milestones, and if a product is approved, to commercialize it.

Partnerships involving development and commercialization of our therapeutic candidates, including our existing exclusive license to Shionogi, pose numerous risks to us, including the following:

- partners have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- partners may de-emphasize or elect not to pursue development or commercialization programs based on studies or trials results, changes in the partners' strategic focus, including as a result of a sale or disposition of a business unit or development function or a business combination involving the partner, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- partners may delay or abandon preclinical studies or clinical trials for our therapeutic candidates, provide insufficient funding for such programs, repeat or conduct new studies or trials or require a new formulation of a therapeutic candidate;
- partners could independently develop, or develop with third parties, therapeutic candidates that compete directly or indirectly with our therapeutic candidates if the partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a partner with marketing and distribution rights to multiple therapeutic candidates may not commit sufficient resources to the marketing and distribution of our therapeutic candidates relative to others;
- partners may not recognize, properly obtain, maintain, defend or enforce our intellectual property rights or may use our intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our intellectual property or expose us to potential litigation or other intellectual property-related proceedings;
- disputes may arise between the partners and us that result in the delay or termination of the research, development or commercialization of our therapeutic candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- partnerships may be terminated by the partner, and, if terminated, may result in our need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates; and

- the strategic arrangements we have entered into may not lead to development or commercialization of our therapeutic candidates in the most efficient manner or at all.

Failure to recognize the benefit of strategic collaborations or partnerships we have entered or may enter in the future could adversely affect our business, financial condition, results of operations and prospects.

We face risks associated with new companies we may create, such as joint ventures and spin-outs.

Part of our business model includes creating business partnerships and new corporate entities to develop and potentially commercialize therapeutic targets identified through our Compass platform that are outside of our core area of expertise. For example, in 2020, we formed Broadwing Bio LLC, a spin-out company with Alloy Therapeutics, Inc., or Alloy, to develop antibody therapies for ANGPTL7 and another undisclosed target in ophthalmic diseases. Going forward, we may create or acquire interests in more joint venture enterprises, spin-outs, and other entities to execute our business strategy. These business collaborations involve risks that our partners may:

- have economic or business interests or goals that are inconsistent with or adverse to ours;
- take actions contrary to our requests or contrary to our policies or objectives, including actions that may violate applicable law;
- be unable or unwilling to fulfill their obligations under the relevant joint venture and spin-out agreements;
- have financial or business difficulties;
- consume the time and attention of our senior executives, who may serve on the board of such companies;
- take actions that may harm our reputation; or
- have disputes with us as to the scope of their or our rights, responsibilities and obligations.

We will not be able to fully control all aspects of the operations of these partnerships or entities, and we may not have full visibility or control over the operations of these enterprises, including their business decisions, compliance practices or their filing, maintenance, protection and enforcement of intellectual property rights, among others. For example, although we have certain opt-in rights to jointly develop and commercialize certain therapeutic candidates developed through our spin-out company with Alloy, we do not have the power to control the operations of Alloy, which owns the applicable programs and therapeutic candidates and the associated intellectual property rights. In addition, if these entities seek further financing, we may be required to contribute additional cash to maintain our equity stake in these entities or our equity stake may be diluted and our investment impaired.

Our present partnerships or spin outs may not be successful. We may have disputes or encounter other problems with respect to our present or future partners, and our agreements may not be effective or enforceable in resolving these disputes. We may not be able to resolve such disputes and solve such problems in a timely manner or on favorable economic terms, or at all. Any failure by us to address these potential disputes or conflicts of interest effectively could have a material adverse effect on our business, prospects, financial condition, results of operations or cash flows.

We rely on third parties to conduct current and future clinical trials, and those third parties may not perform satisfactorily or at all, including failing to meet deadlines for completing such trials, failing to satisfy legal or regulatory requirements or terminating the relationship.

We rely, and expect to continue to rely, on third-party CROs to conduct any current and future clinical trials for our therapeutic candidates. We currently do not plan to conduct any clinical trials independently. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities.

Our reliance on these CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected, and we will be responsible for ensuring our clinical trials are conducted in compliance with applicable laws and regulation, including good clinical practices.

If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our therapeutic candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our therapeutic candidates, which may adversely affect our business, financial condition, results of operations and prospects.

We rely on third parties to manufacture our clinical product supplies and therapeutic candidates and we may not be able to obtain adequate supplies at a reasonable cost or in a timely manner.

The process of manufacturing pharmaceutical products is complex and highly regulated. We do not have any manufacturing facilities or plans to establish manufacturing capabilities in the near future. We rely, and expect to continue to rely, on third parties, including foreign manufacturers, for the manufacture of our therapeutic candidates for preclinical and clinical testing, development purposes, to support regulatory application submissions, as well as for commercial manufacture if any of our therapeutic candidates obtain marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our therapeutic candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. In addition, global health crises or geopolitical conflict may result in disruptions to the operations or an extended shutdown of certain businesses, which could include certain of our contract manufacturers. Further, as our therapeutic candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, we are likely to alter various aspects of the development program, such as manufacturing methods, to optimize processes and results, which may result in additional cost or delay.

We have only limited supply arrangements in place with respect to our therapeutic candidates, and these arrangements do not extend to Phase 3 clinical or commercial supply. We acquire many key materials on a purchase order basis. As a result, we may not have long-term committed arrangements with respect to aspects of our therapeutic candidates and other materials. We will need to establish one or more agreements with third parties to develop and scale up the drug manufacturing process, conduct testing, and generate data to support a regulatory submission, and may be unable to do so on favorable terms. If we obtain marketing approval for any of our therapeutic candidates, we will need to establish an agreement for commercial manufacture with a third party.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not limited to:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing, and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter, or other enforcement action by FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible infringement, misappropriation, violation or unauthorized disclosure of our intellectual property and proprietary rights, including our trade secrets, know-how and other confidential information;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- competition with other companies for access to manufacturing capacity;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside of the United States. If the FDA determines that our contract manufacturing organizations, or CMOs, are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Further, we rely on third parties located in China for some of our contract manufacturing, and we expect to continue to use such third-party manufacturers for such purposes. For any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the BIOSECURE Act, a version of which was passed in the U.S. House of Representatives, but was not passed by the U.S. Senate in 2024, and a revised version of which was recently passed by the U.S. Senate in 2025, but will be subject to the reconciliation process, would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract as well as authorize the U.S. government to name additional Chinese "biotechnology companies of concern," subject to certain "grandfathering" provisions that provide that the BIOSECURE Act's prohibitions will not apply for five years to pre-existing contracts and agreements entered into prior to the legislation's effective date. The BIOSECURE Act has in the past and may in the future define a "biotechnology company of concern" to include WuXi Apptec and its affiliates, or WuXi. Although the BIOSECURE Act has not yet become law, it or a substantially similar bill may be passed or proposed again. We are currently parties to agreements with WuXi, pursuant to which WuXi provides development and manufacturing services to us. If these bills become law, or similar laws are passed, we may be restricted in our ability to work with WuXi and other Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. As a result, we may need to seek alternative CMO relationships, but we expect that the grandfathering provision will provide adequate time to identify and execute agreements with alternative CMOs. While we believe we will be able to identify and contract with such alternative CMOs, we cannot predict the terms of any such alternative arrangement nor what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation. In addition to the BIOSECURE ACT, any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug, packaging and other services being interrupted or limited, which could harm our business.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs for preclinical and clinical testing cannot perform as agreed, we may be required to replace such CMOs. Although we believe that there are several potential alternative manufacturers who could manufacture our therapeutic candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or global health crises. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our therapeutic candidates may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

We or some of our suppliers may experience disruption to our or their respective supply chain due to the effects of macroeconomic conditions, which could delay, prevent or impair our development or commercialization efforts.

We or our third-party suppliers may be affected by macroeconomic events and conditions, including inflation, interest rate fluctuations, new or changing tariff policies or trade restrictions, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, increasing financial market volatility and uncertainty, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. Supply chain disruptions could negatively impact our cost of materials and production processes. For example, the United States has announced tariffs on many goods imported from specified nations, including China and those in the European Union. In addition, recent media reports have suggested potential increased tariffs for pharmaceutical products, which may impact our supply chain and create uncertainty in the broader pharmaceutical industry. If we or certain third parties with whom we work are unable to obtain clinical trial supplies or pharmaceutical products in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, or if the costs of such materials increase due to tariffs, trade restrictions or other factors, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Our reliance on third parties requires us to share certain of our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third parties may require us to share certain of our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to government regulation

The FDA regulatory approval process is lengthy and time-consuming.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of our therapeutic candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States. Our current lead programs, MZE829 and MZE782, are both small molecules and will be regulated as drugs. We are not permitted to market any drug in the United States until we receive approval of the respective NDA. We have not previously submitted an NDA to the FDA or made similar submissions to comparable foreign regulatory agencies. An NDA must include extensive preclinical and clinical data and supporting information to establish the therapeutic candidate's safety and effectiveness for each desired indication, which takes many years to collect through clinical and preclinical testing of the therapeutic candidate and is subject to a high failure rate. Further, the NDA must also include significant information regarding the chemistry, manufacturing, and controls for the product, including storage and handling of the product. The manufacturing facility is also required to maintain a compliance status acceptable to the FDA. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable foreign regulatory agencies will interpret the results as we do, and more trials could be required before we submit an NDA, or other foreign marketing application. Further, the FDA may call an advisory committee meeting to discuss the product and its intended use, as well as scientific and regulatory issues related to the product and the NDA, which may further delay approval of our therapeutic candidates or lead to restrictions on their intended use.

We, as a company, have limited experience in submitting INDs in the United States and we do not have experience in obtaining regulatory approval to initiate clinical trials in any other jurisdiction. Nor do we have experience in manufacturing or in quality assurance in order to market our therapeutic candidates in the United States or in any other jurisdiction.

We have limited experience in submitting INDs in the United States and we do not have experience in obtaining regulatory approval to initiate clinical trials in any other jurisdiction. Nor do we have experience in manufacturing or in quality assurance in order to market a drug and we expect to rely on third-party CROs, CMOs or other third-party consultants or vendors to assist us in this process. Our inexperience may result in failure or delay in obtaining permission to initiate clinical trials or in obtaining marketing approval for our therapeutic candidates. If we are unable to obtain regulatory and marketing approval for our therapeutic candidates, or experience significant delays in our efforts to do so, our business could be substantially harmed.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our therapeutic candidates from being marketed abroad, and any approval we are granted for our therapeutic candidates in the United States would not assure approval of therapeutic candidates in foreign jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and may involve additional testing. The time required to obtain approval from foreign regulatory authorities may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before such product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

If we decide to pursue a fast track designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

Some of our therapeutic candidates may be intended to treat serious or life-threatening conditions and may demonstrate the potential to address an unmet medical need for such conditions, and as such they would be eligible for expedited processes within the FDA such as fast track designation. The FDA has broad discretion whether or not to grant such designation, so even if we believe a particular therapeutic candidate is eligible for this designation, we cannot guarantee that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

If we decide to pursue accelerated approval for any of our therapeutic candidates, it may not lead to a faster regulatory review or approval process and does not increase the likelihood that our therapeutic candidates will receive marketing approval.

As part of our business strategy, we may pursue accelerated approval for one or more of our therapeutic candidates. Under the FDA's accelerated approval program, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful product benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. We may seek accelerated approval for one or more of our therapeutic candidates on the basis of a surrogate endpoint that we believe is reasonably likely to predict clinical benefit.

If any of our therapeutic candidates receive accelerated approval from the FDA, we will be required to undergo one or more confirmatory clinical trials. If such a therapeutic candidate fails to meet its safety and efficacy endpoints in such confirmatory clinical trials, the FDA may withdraw the accelerated approval.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm clinical benefit. In addition, the enactment of the Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

There is no assurance that any therapeutic candidate will successfully advance through its confirmatory clinical trial(s). Therefore, even if a therapeutic candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date.

Even if we, or any of our partners, obtain marketing approval for our therapeutic candidates, the terms of approvals, ongoing regulation of our product, including enforcement of post-marketing requirements by regulatory agencies or other post-approval restrictions, may require the expenditure of substantial resources, which could materially impair our ability to generate revenue. If we, or any of our partners or manufacturers, fail to comply with all regulatory requirements or experience unanticipated problems with our products, when and if any of them are approved, we could be subject to substantial penalties, including withdrawal of our product from the market.

Any therapeutic candidate for which we, or any of our partners obtain marketing approval, as well as the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

For instance, even if marketing approval of a product is granted, the FDA may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, including the adoption and implementation of a REMS.

We, or any of our partners, must also comply with requirements concerning advertising and promotion for any of our therapeutic candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the therapeutic candidate's approved labeling. Thus, we, and any partners, will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third-party manufacturers, and any partners and their third-party manufacturers, and our CMOs would be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any partners, obtain marketing approval for one or more of our therapeutic candidates, we, any partners and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA as well as other federal and state agencies, including the U.S. Department of Justice, enforce and closely regulate compliance with all requirements governing drug products, including those requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients using our products;
- restrictions on such products, manufacturers or manufacturing processes;
- modifications to the labeling or restrictions on the marketing of a product;
- restrictions on distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning or untitled letters;
- withdrawal or recall of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential partners;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future partner with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of our products can also result in significant financial penalties.

If generic versions of our small molecule therapeutic candidates are approved, our revenue and results of operations would be adversely affected.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, permits the FDA to approve abbreviated NDAs, or ANDAs, for generic versions of small molecule branded drugs. We refer to this process as the ANDA process. The ANDA process permits a competitor to obtain marketing approval for a drug with the same active ingredient as a branded drug but does not generally require the conduct and submission of clinical efficacy studies for the generic product. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product is bioequivalent to the branded product. The Hatch-Waxman Amendments require an ANDA applicant seeking FDA approval of its proposed generic product prior to the expiration of any patents we may list in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) to certify that the applicant believes that our patents are invalid or will not be infringed by the manufacture, use or sale of the drug for which the application has been submitted (a Paragraph IV certification) and notify us of such certification (a Paragraph IV notice).

Pursuant to the Hatch-Waxman Amendments, with regard to a drug that has received five years of marketing exclusivity as a result of being a new chemical entity, or NCE, FDA cannot receive any ANDA seeking approval of a generic version of that drug during the five-year period of exclusivity unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. Accordingly, potential competitors will be permitted to submit ANDA applications for proposed generic versions of any small molecule products for which we obtain approval four or five years from the date of such approval was granted.

Upon receipt of a Paragraph IV notice, the Hatch-Waxman Amendments allow us, with proper basis, to bring an action for patent infringement against the ANDA filer, asking that the proposed generic product not be approved until after our patents expire. If we commence a lawsuit within 45 days from receipt of the paragraph IV notice, the Hatch-Waxman Amendments provide a 30-month stay, during which time the FDA cannot finally approve the ANDA application. If the litigation is resolved in favor of the ANDA applicant during the 30-month stay period, the stay will be lifted and the FDA may approve the ANDA if it is otherwise ready for approval. The discovery, trial and appeals process in such a lawsuit is costly, time consuming, and may result in generic competition if the ANDA applicant prevails.

Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our current and future arrangements with such healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the federal transparency requirements under the ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to, and ownership and investment interests held by, physicians, as defined by such law, and their immediate family members; and
- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, 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 require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations 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, marketing expenditures, or drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives. State and non-U.S. laws that also govern the privacy and security of personal information (including health information in some circumstances), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and may affect pricing and third-party payment for our therapeutic candidates and decrease the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post-approval activities and affect pricing and third-party payment for our therapeutic candidates, which could negatively affect our ability to profitably sell any therapeutic candidates for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act in August 2022, which allows, among other things, the Department of Health and Human Services, or HHS, to negotiate the selling price of a statutorily specified number of drugs and biologics each year that the Centers for Medicare & Medicaid Services, or CMS, reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the Inflation Reduction Act's price negotiation requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The Inflation Reduction Act also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. In addition, the law eliminated the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and establishing a new manufacturer discount program, which requires manufacturers, in order for their drugs to be covered by Medicare Part D, to provide statutorily defined discounts on their brand (NDA) drugs dispensed to Part D enrollees. The Inflation Reduction Act also extends premium enhanced subsidies for lower income individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, but those subsidies are set to expire at the end of 2025 unless they are extended by Congress. The Inflation Reduction Act permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the Inflation Reduction Act may be subject to various penalties, some significant, including civil monetary penalties. These provisions have begun taking effect progressively starting in 2023, although they may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits. Thus, it is unclear how the Inflation Reduction Act will be implemented but it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and therapeutic candidates. The One Big Beautiful Bill Act, or OBBBA, which was recently signed into law, reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly for Medicaid programs. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

In addition, at the state level, individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures may be adopted in the future. Such reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Disruptions at the FDA and other government agencies caused by, among other factors, funding shortages 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, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. In addition, there is substantial uncertainty regarding new regulatory initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies on which our operations may rely, including those 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 therapeutic candidates to be reviewed and/or approved by necessary government agencies, which may adversely affect our business, financial condition, results of operations and prospects. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

FDA-regulated industries, such as ours, face uncertainty with regard to the regulatory environment we will face as we proceed with research, development and commercialization. Some of these efforts have manifested to date as efforts to reduce the size of the federal government, including large-scale reductions in force at the FDA. The loss of key personnel at the FDA, including those in leadership positions, is likely to impact operations at the FDA, which could result in, among other things, delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development, longer review times and delays in obtaining regulatory approvals for our product candidates. There remains general uncertainty regarding future activities. New executive orders, regulations, policies or guidance could be issued or promulgated that adversely affects us or creates a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance, there could be a material adverse effect on us and our business.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our therapeutic candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed, or become more expensive.

Even if we are able to commercialize a drug candidate, coverage and adequate reimbursement may not be available or such drug candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed or may require us or our partners to conduct clinical trials that compare the cost-effectiveness of our therapeutic candidates to other therapies to obtain reimbursement or pricing approval. In many countries, the pricing review period begins after regulatory approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Adverse pricing limitations may hinder our ability to recoup our investment in one or more therapeutic candidates, even if any of our current or future therapeutic candidates obtain regulatory approval.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third-party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more drugs to market, these drugs may not be considered cost-effective, and the amount reimbursed for any drugs may be insufficient to allow us to sell our drugs on a competitive basis. Moreover, in the United States, no uniform policy requirement for coverage and reimbursement for drugs exists among third-party payors, which may result in significant variations in coverage and reimbursement from payor to payor. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If the price we are able to charge for any drugs we develop, or the coverage and reimbursement provided for such drugs, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain therapeutic candidates outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain therapeutic candidates outside of the United States, which could limit our growth potential and increase our development costs.

Failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA accounting provisions.

If we, or any third-party contractors we engage, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our third-party contractors are subject to numerous foreign, federal, state and local 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. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, discharge or injury from these materials. In the event of contamination, discharge or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance. We could be subject to civil damages and criminal penalties in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. Further, it is possible that the materials we use could contaminate another party's property. In addition, claimants may sue us for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets and our ability to pay the liability.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability, including claims that may arise from pollution from chemical, radioactive or biological materials, or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Our partners may also be working with various types of hazardous materials in connection with our collaborations.

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, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have and expect to continue to have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities, including those in China, to increase over time. We expect to continue to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior 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.

We are, and may in the future be, subject to stringent and changing 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; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and otherwise process (which we refer to as process or processing) certain personal information and other sensitive information, including our proprietary and confidential business data, trade secrets, employee data, intellectual property, data we or our CROs collect about trial participants in connection with clinical trials, and other sensitive data. The global data protection landscape is rapidly evolving and we are and may increasingly become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, directives, industry standards, external and internal privacy and security policies, contractual requirements and other obligations that govern the processing of sensitive or confidential information by us and on our behalf, and we may be subject to new or additional data protection laws and regulations and face increased scrutiny from regulators as our business grows. The legislative and regulatory landscape for data privacy and security continues to evolve in jurisdictions worldwide, and there has been an increasing focus on these issues with the potential to affect our business, financial condition, results of operations and prospects.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security that could result in regulatory investigations, fines or injunctions, as well as civil claims including class actions, and reputational damage. Implementation standards, interpretation, and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal or external policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, data privacy laws, and other similar laws. For example, all 50 states and the District of Columbia have enacted breach notification laws that may require us to notify patients, customers, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential information experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, HIPAA, as amended by HITECH, imposes among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the processing of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (as amended by the California Privacy Rights Act of 2020), or CCPA, imposes obligations on businesses that meet certain thresholds that process the personal information of California residents (including employees based in California). These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal information, which includes a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA could increase compliance costs and potential liability. The 2020 amendments to the CCPA also created the California Privacy Protection Agency, a new enforcement agency whose sole responsibility is to enforce the CCPA and is empowered to create new CCPA regulations. Other states, such as Virginia, Indiana, Oregon, Texas, Tennessee, Montana, Iowa, Delaware, Connecticut, Utah, Washington and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. In addition to government activity and private rights of actions provided by some of the state privacy laws, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

Around the world, many countries have privacy and data protection laws that create potentially complex compliance issues for us, our future customers, and strategic partners. For example, outside the United States, the EU's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to €20 million or 4% of annual global revenue, whichever is greater. Such fines would be in addition to (i) the rights of individuals to sue for damages in respect of any data privacy breach which causes them to suffer harm, (ii) the right of individual member states to impose additional sanctions over and above the administrative fines specified in the GDPR and (iii) the ability of supervisory authorities to impose orders requiring companies to modify their practices. If we are found not to be compliant with the GDPR or similar requirements, we may be subject to significant fines and the risk of civil litigation. Among other requirements, the GDPR and UK GDPR (and certain other foreign jurisdictions) regulate the cross-border transfer of personal data, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or the United Kingdom to countries such as the United States which are not considered by the EU or United Kingdom to provide adequate protection of personal data). In October 2022, the EU-U.S. Data Privacy Framework, or EU-U.S. DPF, was implemented, and the European Commission adopted an adequacy decision on July 10, 2023 that set conditions for personal data transfers from the EU to certified companies in the United States without additional safeguards in place. However, this decision will likely face legal challenges and ultimately may be invalidated by the Court of Justice of the EU. On October 12, 2023, a UK-U.S. Data Bridge came into force to operate as an extension of the EU-U.S. DPF to facilitate transfers of personal data between the United Kingdom and certified entities in the United States. Such Data Bridge could not only be challenged, but also may be affected by any challenges to the EU-U.S. DPF. Furthermore, in June 2021, the European Commission adopted new standard contractual clauses under the GDPR for transfers of personal data outside the European Economic Area to countries that the European Commission has not deemed to provide an adequate level of protection for such personal data. While we strive to adhere to all requirements to transfer information across jurisdictions using safeguards endorsed by government guidance (such as using the Standard Contractual Clauses approved by the European Commission), we must still adapt to changing guidance and will follow any anticipated litigation closely. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we may have to implement revised standard contractual clauses for existing arrangements within required time frames; and/or it could adversely affect our business, financial condition, results of operations and prospects.

Any such changes in the law related to the use of personal information or data could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate or may operate in the future. Complying with these numerous, complex, conflicting, and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs, partners or another third party, which may adversely affect our business, financial condition, results of operations and prospects., financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security that could prove to be more burdensome as laws and regulations evolve. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', clinical trial participants' and employees' sensitive information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Although we endeavor to comply with our public statements and documentation regarding our handling of personal information, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

Risks related to commercialization of our therapeutic candidates

We face significant competition in an environment of rapid technological change and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies or technologies that are more advanced or effective than ours, which may harm our business and financial condition, and our ability to successfully market or commercialize our therapeutic candidates.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from major pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions, among others.

Any therapeutic candidates that we or our partners successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future that are approved to treat the same indications for which we or they may obtain approval for our therapeutic candidates. It is also possible that we or our partners may face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, include, but are not limited to their efficacy, safety, convenience, adoption by prescribers, price, level of generic competition, and availability of reimbursement.

We may face competition from companies developing therapies for CKD and related nephropathies, including but not limited to established therapies including renin-angiotensin-aldosterone system, or RAAS, inhibitors, SGLT2 inhibitors and glucagon-like peptide 1, or GLP-1 agonists, as well as novel mechanisms such as therapies being developed by various companies targeting different pathways implicated in CKD progression.

While there are currently no approved therapies for APOL1-mediated kidney disease, or AMKD, we are aware of companies advancing therapeutic candidates in clinical trials that target APOL1.

Our second most advanced lead program, MZE782, is a small molecule targeting SLC6A19, a novel target in CKD and PKU. While there are no currently approved therapies directly modulating SLC6A19, we may face competition from other companies pursuing programs targeting SLC6A19 or alternative approaches for kidney and metabolic indications.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Further, precision medicine is a rapidly developing field, with increasing usage within the pharmaceutical and biotechnology industry of machine learning and AI technologies to analyze genetic data. While we believe our Compass platform has advantages over potential competitors based on our experience in variant functionalization, our access to genetic databases, and the length of time that we have been engaged in developing precision medicine, other companies may have greater resources or the ability to acquire more advanced technology to identify targets and may acquire access to the same genetic data that we utilize. We may not be able to keep up with the pace of innovation that is occurring in our field, and we may face increasing competition in developing precision medicines.

Our commercial opportunity could be reduced or eliminated if our 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. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Even if our Compass platform is effective as a research tool, we may be unable to develop or commercialize new drugs, therapies or other products based on discoveries from our Compass platform.

Even if our Compass platform performs its intended functions, we may be unable to use the discoveries resulting from the platform to produce new therapies. Despite recent scientific advances in the life sciences and our improved understanding of biology, the roles of genes and proteins and their involvement in diseases and in other life processes is not well understood. Therefore, notwithstanding any potential promising results in earlier studies or clinical trials, we may face significant setbacks in current or future studies or clinical trials. If we are unable to use our platform discoveries to develop and market new drugs or therapies, our business may fail or we may never become profitable.

We, or the third parties we rely on, may be unable to develop the diagnostic tests or clinical assays to successfully advance our therapeutic candidates through clinical trials or commercialization.

Some or all of our therapeutic candidates may require companion diagnostic tests for clinical trials or commercialization. If we are unable to successfully develop the applicable companion diagnostic tests, experience significant delays in doing so, or rely on third parties in the development of such companion diagnostic tests, or if we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our therapeutic candidates, and we do not obtain or face delays in obtaining FDA approval of a companion diagnostic test, the full commercial potential of our therapeutic candidates and our ability to generate revenue will be materially impaired.

Our approach to drug discovery and developing therapeutic candidates relies on human genetics and functional genomics to identify targets for therapeutic intervention as well as predictive biomarkers to evaluate the effects of our therapeutic candidates. For those therapeutic candidates that advance to clinical trials, predictive biomarkers, such as a specific genetic screen, may become necessary for subject selection and thus may require the incorporation of a diagnostic test, or companion diagnostic, into our clinical trial design. If required, we may engage one or more third-party partners to co-develop the necessary companion diagnostic.

If safe and effective use of any of our therapeutic candidates depends on a companion diagnostic test, then the FDA generally will require approval or clearance of that companion diagnostic, before or at the same time that the FDA approves our therapeutic candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. In the past, FDA has issued guidance on the development of companion diagnostics generally as well as for specific disease categories. We will continue to evaluate the impact of FDA guidance on our companion diagnostic development and strategy. This guidance and any future guidance or policies from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our therapeutic candidates and result in delays in regulatory approval. We may be required to conduct additional studies or clinical trials to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business, financial condition, results of operations and prospects.

We expect to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic candidates that require such tests. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our therapeutic candidates, whether before or after the therapeutic candidate obtains marketing approval, we, and/or future partners, may encounter difficulties in developing and obtaining approval for such therapeutic candidate. If we or our third-party partners experience any delay in developing or obtaining regulatory approval of a companion diagnostic, we may be unable to enroll enough patients in future clinical trials, the development of our therapeutic candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our therapeutic candidates.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any therapeutic candidate for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either by ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a therapeutic candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include, but not limited to:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales and marketing capabilities and must rely on third parties to market and sell our products, our revenue from product sales and our profitability, if any, are likely to be lower than if we ourselves were to market and sell any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to market and sell our therapeutic candidates or may be unable to do so on terms that are acceptable to us. Any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our therapeutic candidates.

Even if any of our therapeutic candidates receives marketing 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.

If any of our therapeutic candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. If our therapeutic candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our therapeutic candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the acceptance of our therapeutic candidates as front-line treatment for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved for our therapeutic candidates by the FDA;
- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing, sales and distribution support;
- publicity for our therapeutic candidates and alternative treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage, adequate reimbursement and favorable pricing policies;

- the timing of any required marketing approval;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

Even if our therapeutic candidates were to display a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of such therapeutic candidates will not be fully known until after they are launched.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any therapeutic candidates that we may develop alone or with partners.

Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory approval, may exhibit unforeseen side effects. We face an inherent risk of product liability exposure related to the testing of our therapeutic candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our therapeutic candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any therapeutic candidates that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

As a clinical-stage company, we currently hold product liability insurance coverage for our clinical trials. Insurance coverage is increasingly expensive. 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. A successful product liability claim or series of claims brought against us could decrease our cash and could adversely affect our business, financial condition, results of operations and prospects.

Our estimated market opportunities for our therapeutic candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.

From time to time we may provide estimates of addressable markets and market opportunities for our therapeutic candidates, which are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove not to be accurate, particularly given the relatively early stage of our therapeutic candidates. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this Quarterly Report on Form 10-Q. If this third-party or internally generated data prove to be inaccurate or if we make errors in our assumptions based on that data, or if the facts underlying our assumptions change over time, our actual market may be more limited than we estimate it to be. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business. Our estimates of our market opportunities should not be taken as indicative of our ability to grow our business.

Moreover, prices for novel approved treatments must often be set high in order to recover the sponsor's development and manufacturing costs, fund additional research and achieve profitability, and we may be unable to obtain the price necessary to achieve these things. We may also need to fund patient support programs upon the marketing of a therapeutic candidate, which would negatively affect the revenue of a therapeutic candidate. We may be unable to maintain or obtain sufficient therapy sales volumes at a price high enough to justify our development efforts and our sales, marketing and manufacturing expenses.

Risks related to our business operations

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the development and management expertise of our scientific founders who are leading researchers in genetics and bioinformatics, as well as the other principal members of our management, scientific and clinical team. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Moreover, we might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area, where we are headquartered, and we may be required to expend significant financial resources in our employee recruitment and retention efforts. Many pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer operating histories in the industry than we do. They also may provide candidates with more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, including personnel with clinical development expertise, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

We also rely on scientific, clinical, and other technical advisors and consultants to assist us with our clinical development programs. Our future success will depend in part on our ability to engage such advisors and consultants with the necessary expertise. In addition, these advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. They may also have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, and in connection with our recent transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in clinical development and, as our therapeutic candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. We have to manage additional relationships with partners, suppliers and other organizations as part of our ongoing and anticipated clinical trials, and we expect to continue to have to manage additional relationships with partners, suppliers and other organizations in the future. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. In addition, we may need to expand our facilities, including laboratory operations, and may be unable to do so on commercially reasonable terms, or at all. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our current or future employees, clinical trial investigators, CROs, CMOs, consultants, vendors and partners may engage in misconduct or other improper activities, including non-compliance with regulatory requirements, violations of regulatory standards, and insider trading.

We are exposed to the risk of misconduct by our current or future employees, clinical trial investigators, CROs, CMOs, consultants, vendors and partners. Misconduct by these parties could include fraud or intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory agencies, (ii) manufacturing or clinical standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation, or improper or unauthorized use of AI or machine learnings tools that result in the disclosure of confidential information or reliance on inaccurate information.

We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee 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 comply with laws or regulations. If any actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, such actions could adversely affect our ability to operate our business and our results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations.

Our business is dependent on the integrity of information technology systems and failure of such systems could disrupt our business.

Like most companies, we depend on the efficient and uninterrupted operation of our information technology and communications systems and those of our third-party vendors, contractors or consultants. Such systems may fail or suffer security breaches, cyberattacks, loss or leakage of data and other disruptions, which could cause adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

We, and third parties on whom we depend, are increasingly dependent on information technology systems, infrastructure and data to operate our and their businesses. In the ordinary course of business, we process confidential information (including but not limited to intellectual property, proprietary business data and patient data). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our information technology systems and operations to third parties, and as a result we rely on and manage a number of third-party vendors and other contractors and consultants who have access to and process our confidential information.

Although we are still in the process of implementing our internal security controls, policies and other measures, we have taken steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, 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. Despite the implementation of these security measures, our information technology systems and those of our third-party vendors and other contractors and consultants have been in the past and may be in the future potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third-party service providers, natural disasters, terrorism, war, global pandemics, and telecommunication and electrical failures. We may also experience security incidents from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners and/or other third parties, including theft, fraud or unauthorized access to or use of our information technology systems, or attack or damage from hacking, cyberattacks or supply chain attacks by malicious third parties and sophisticated nation-state and nation-state-supported actors (including the deployment of harmful computer viruses and malware, ransomware, denial or degradation-of-service attacks, phishing attacks and other social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, impede our ability to conduct business, delay our financial reporting or lead to data leakage.

While we have a security consultant provide annual assessments on our systems vulnerabilities, the risk of a security incident or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, continues to increase as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Cyberattacks or security incidents could remain undetected for an extended period, which could potentially result in significant harm to our information technology systems, as well as unauthorized access to the information stored on and transmitted by our information technology systems. Even if identified, the full extent of a cyberattack or security incident may not be determined immediately and we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Moreover, recovery of our information technology systems may be additionally hampered where we have outsourced the operation of information technology systems and information storage to third parties. Any breach, loss or compromise of confidential information may also subject us to liability, government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); breach notification and additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class action litigation); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Further, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Significant disruptions of our information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property or proprietary business information) and claims by our counterparties that we have failed to comply with legal or contractual obligations, which could result in financial, legal, business, and reputational harm to us.

There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate to protect us from liabilities and damage and we may not have adequate insurance coverage to cover losses, or all types of costs, expenses and losses, we could incur with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We utilize third-party open source software, and any failure to comply with the terms of one or more of these open source software licenses could adversely affect our business, subject us to litigation, or create potential liability.

Our Compass platform utilizes software licensed by third parties under any one or more open source licenses, including the Apache 2.0 License, MIT, BSD variants, and others, and we expect to continue to incorporate open source software in our business in the future. We cannot ensure that we have effectively monitored our use of open source software, or validated the quality or source of such software, or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures.

Companies that incorporate open source software into their products have, from time to time, faced claims challenging the use of open source software and compliance with open source license terms. We could be subject to similar suits by parties claiming ownership of what we believe to be open source software or claiming non-compliance with open source licensing terms, which could result in litigation that may cause us to be required to disclose our proprietary source code based on our modifications of open source code, incur expenses and be liable for damages and such litigation could distract our personnel from their normal responsibilities.

Furthermore, there are an increasing number of open source software license types, almost none of which have been interpreted by U.S. or foreign courts, and there is a risk that such licenses to which we are subject to could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market or provide our products or services. If we are held to have breached or failed to fully comply with any of the terms and conditions of an open-source software license, we could face claims for breach of contract, intellectual property infringement or misappropriation or other liability, or be required to seek costly licenses from third parties that may not be available on commercially reasonable terms, or at all. By the terms of certain open source licenses, we could be required to release the source code of our proprietary software, and to make our proprietary software available under open source licenses, if we combine our proprietary software with open source software in a certain manner. In the event that portions of our proprietary software are determined to be subject to an open source license, we could be required to publicly release the affected portions of our source code, re-engineer all or a portion of our Compass platform, or otherwise be limited in the licensing of our Compass platform, each of which could reduce or eliminate the value of our Compass platform. Disclosing our proprietary source code could allow our competitors to create similar products with lower development effort and time, which would materially and adversely affect our business, financial condition, results of operations and prospects. Furthermore, any such re-engineering or other remedial efforts could require significant additional research and development resources, and we may not be able to successfully complete any such re-engineering or other remedial efforts.

Further, in addition to risks related to license requirements, use of certain open source software carries greater technical and legal risks than does the use of third-party commercial software. For example, open source software is generally provided without any representations, indemnity, support or warranties or other contractual protections regarding infringement or the quality of the code, including the existence of security vulnerabilities. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. To the extent that our Compass platform depends upon the successful operation of open source software, any undetected errors or defects in open source software that we use could prevent the deployment or impair the functionality of our systems and injure our reputation. In addition, the public availability of such software may make it easier for others to compromise our Compass platform. Any of the foregoing risks could materially and adversely affect our business, financial condition and results of operations.

The use of new and evolving technologies, such as AI in our operations may require us to expend material resources and may present risks and challenges that can impact our business, including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We incorporate AI solutions, including machine learning, into our Compass platform. There are significant risks involved in utilizing AI and no assurance can be provided that the usage of AI will enhance our business or assist our business in becoming more efficient or profitable. The use of certain AI technology can give rise to intellectual property risks, including compromising the privacy and security of our proprietary technologies and leading to claims of intellectual property infringement, misappropriation or other violation. In addition, AI may have errors or inadequacies that are not easily detectable. If the data used to train AI or the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, overbroad or biased, our business, financial condition, and results of operations may be adversely affected.

Additionally, we expect to see increasing government and supranational regulation and ethical concerns related to AI use, which may also significantly increase the burden and cost of research, development and compliance in this area. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our technology and products to help ensure that AI is implemented in accordance with applicable laws and regulations and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The legal landscape and subsequent legal protection for the use of AI remains uncertain, and development of the law in this area could impact our ability to enforce our proprietary rights or protect against infringing uses. If we do not have sufficient rights to use the data on which AI relies or to the outputs produced by AI applications, we may incur liability through the violation of certain laws, third-party privacy or other rights or contracts to which we are a party.

Our third-party vendors, contractors and consultants may also incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to intellectual property, privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses generated in tax years beginning after December 31, 2017 will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited to 80% of current year taxable income. In addition, both our current and our future unused losses and other tax attributes (such as research credits) may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We had a Section 382 study prepared which covered the period from inception through December 2025. The study concluded that several ownership changes occurred since our inception. However, it was determined that the annual available NOLs under Section 382 will be sufficient to utilize in their entirety prior to their respective expiration years. It is possible that we may undergo additional ownership changes in the future, including as a result of the issuance of common stock pursuant to our initial public offering completed in February 2025 or future transactions or events that may be outside of our control. As a result, even if we attain profitability, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result of the foregoing, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets, joint ventures and spin-outs. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including, but not limited to:

- exposure to unknown liabilities;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in integrating the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations and prospects, which could lead to a decline in our stock price.

Our results of operations and stock price could be adversely affected by general conditions in the global economy and in the global financial markets. For example, a global financial crisis or uncertainty with respect to federal regulations could cause extreme volatility and disruptions in the capital and credit markets. Similarly, increased volatility in interest, inflation and tariff rates and the debt and equity markets, instability in the global banking system, global health crises and pandemics and geopolitical conflict could cause significant instability and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our therapeutic candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our partners and our suppliers, possibly resulting in development or supply disruption. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

Risks related to intellectual property

Our success depends in part on our and our partners' ability to obtain, maintain, enforce and protect our intellectual property and proprietary rights. It is difficult and costly to protect our intellectual property rights and technologies, and we may not be able to ensure their protection. If we are unable to adequately protect our technologies or obtain and maintain patent protection for our technologies and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.

Our commercial success will depend in large part on our and our partners' obtaining, maintaining, enforcing and protecting patent, trademark, trade secret and other intellectual property and proprietary protection in the United States and other countries for our technologies. Our proprietary technologies include our Compass platform, genetic targets identified by our Compass platform, machine learning used by our Compass platform, our methods for developing and testing our therapeutic candidates, our therapeutic candidates themselves, and any therapeutic compounds, molecules or agents related to such therapeutic targets, including their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment. Our commercial success will also depend, in large part, on successfully defending our trademarks, trade secrets, owned patents and patent applications and other intellectual property rights against third-party challenges. We seek to protect our intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our technologies, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our intellectual property position. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our technologies or therapeutic candidates is dependent upon the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property or proprietary rights that cover these activities. If we or our current or future partners are unable to secure and maintain patent, trade secret or other intellectual property or proprietary protection for any technologies or therapeutic candidates we or they develop, or if the scope of the protection secured is not sufficiently broad, our competitors could develop and commercialize technologies or therapeutic candidates similar or identical to ours, and our ability to commercialize any technologies or therapeutic candidates we or our partners may develop or to otherwise compete effectively may be adversely affected.

We have filed patent applications, both in the United States and internationally, protecting our inventions related to our MZE829 and MZE782 candidates as well as our out-licensed programs. Our MZE001 patent portfolio has been exclusively out-licensed to Shionogi, who also has the exclusive right to make decisions regarding the prosecution and enforcement of patents or patent applications within that portfolio. Our UNC13A patent portfolio has been assigned to Trace Neuroscience, Inc., who has the exclusive right to make decisions regarding the prosecution and enforcement of those respective portfolios.

A provisional patent application is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing such provisional application. If we fail to do so, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and for the designation of all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. A PCT application is not eligible to become an issued patent until, among other things, we file one or more national stage patent applications within the applicable time limit, which is generally 30 or 31 months from the PCT application's earliest priority date, depending on the jurisdiction, in the countries in which we seek patent protection. If we fail to file a national phase application in a PCT member state, we may lose our priority date in that member state with respect to the subject matter disclosed in the PCT application, as well as any patent protection in that member state on the inventions disclosed in the PCT application. While we generally intend to timely file non-provisional and national phase patent applications, as applicable, we cannot predict whether any of our current or future patent applications relating to any therapeutic targets, therapeutic candidates or technologies we have identified or may identify in the future will result in the issuance of patents that effectively protect our therapeutic targets, therapeutic candidates or technologies. If we or our partners do not successfully obtain patent protection, or, even if we or they do obtain patent protection, if the scope of the patent protection obtained with respect to any therapeutic target, therapeutic candidate and technology is not sufficiently broad, we or our partners may be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or our partners'.

The patenting process is expensive and time-consuming, and we and our current or future partners may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we or our partners may not pursue or obtain patent protection in all relevant jurisdictions, particularly in markets where translation costs are high. It is also possible that we or our partners will fail to identify patentable aspects of our or their research and development output before it is too late to obtain patent protection. Although we seek to enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, hospitals, independent treatment centers, suppliers, partners and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, 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 be certain that we were the first to make the inventions claimed in our current or future patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in circumstances, including with respect to our exclusive out-licensing or assignment of our MZE001 and UNC13A patent portfolios, where we do not have the right to control the preparation, filing, prosecution, maintenance, defense or enforcement of patents or patent applications covering technologies that we currently, or may in the future, license from or license to third parties, we will be reliant on our licensors or licensees to do so. If our partners are not fully cooperative or disagree with us as to the preparation, filing, prosecution, maintenance, defense or enforcement of any licensed patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications, if any, may not result in issued patents. Moreover, 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 we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we may own or in -license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our therapeutic candidates or technologies will be protectable or remain protected by valid and enforceable patents. In addition, any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing therapeutic candidates in a non-infringing manner. In addition, given the amount of time required for the development, testing, and regulatory review of new therapeutic candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent rights may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and any patents we may own or in-license in the future may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, invalidate, or hold unenforceable, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and therapeutic candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Moreover, some of the patents and patent applications we may own or in-license in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Changes to the 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.

As is the case with other biopharmaceutical companies, our success may be heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011, made a number of significant changes to U.S. patent law, affecting the way patent applications are prosecuted, redefining prior art and providing more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-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. The first-to-file provisions require patent applicants such as us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications. However, circumstances could prevent us from promptly filing patent applications on our inventions. Similar legislation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our future collaboration partners' patent applications and the enforcement or defense of our or our future collaboration partners' issued patents, if any, all of which could harm our business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our intellectual property. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on and weaken our ability to obtain and enforce new patents and patents that we or our collaboration partners might obtain in the future.

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

Although we have issued patents in the United States and other countries and pending patent applications in the United States and other countries, filing, prosecuting, maintaining, enforcing and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our therapeutic candidates, and our patents, the patents of our current and future partners, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our partners' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our partners at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our partners at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time-consuming and could prevent or delay us from developing or commercializing our therapeutic candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our therapeutic candidates and use our technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other intellectual or proprietary rights are enforced against us and found to be valid, enforceable and cover our therapeutic candidates or their compositions, methods of use or manufacturing, third parties owning such intellectual or proprietary rights could seek an injunction prohibiting our ability to develop, manufacture, market and sell our therapeutic candidates and technologies, or we may be required to pay damages, which could be substantial, and we would not be free to manufacture, use or market our therapeutic candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our therapeutic candidates and technologies we use in our business. Our competitors or other third parties may assert infringement, misappropriation or other claims against us alleging, for example, that our therapeutic candidates or technologies we use in our business are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. 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 will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our therapeutic candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our existing therapeutic candidates and any other therapeutic candidates that we may develop or technologies we use in our business may be subject to claims of infringement of the patent rights of third parties. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our therapeutic candidates or technologies we use in our business. If a patent holder believes our therapeutic candidates or technologies we use in our business infringe on its patent rights, the patent holder may sue us even if we have received patent protection for our therapeutic candidates or technologies.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our therapeutic candidates and technologies, including interference proceedings or post-grant challenges before the USPTO. Third parties may also assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of technologies, products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Our analysis of these issues, including interpreting the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our technologies or therapeutic candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining the expiration date of any patent in the United States or abroad that we consider relevant to our therapeutic candidates may be incorrect, which may negatively impact our ability to develop, manufacture, use and market our therapeutic candidates or technologies.

If we were sued for patent infringement, we would need to demonstrate that our therapeutic candidates, technologies or methods of use, manufacturing or other applicable activities 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 successful in doing so. Proving invalidity or unenforceability may be difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing, using or commercializing the infringing therapeutic candidate or technology. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing therapeutic candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims by third parties asserting that we, or our employees or consultants have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees and consultants are currently or have been previously employed at universities or research institutions, or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to develop and commercialize our therapeutic candidates or technologies. Such a license may not be available on commercially reasonable terms or at all and may not be exclusive to us. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

While it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing and the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such additional assignments. Any invention assignment agreements we have with third parties, employees, consultants or contractors may be breached, and it may be difficult or impossible to enforce them. In addition, we have several sponsored research agreements relating to our research and development efforts with various academic institutions. Some of these academic institutions may not have intellectual property assignments or similar agreements with their employees and consultants, or may not permit their employees to assign intellectual property outside the academic institution, which may result in claims by or against us related to ownership of any intellectual property. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and any future patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. In addition, the USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. We may rely on partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with other requirements with respect to licensed patents and patent applications. While an inadvertent lapse may, in some jurisdictions and under certain circumstances, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete and irrevocable loss of a patent or patent rights in the relevant jurisdiction. Noncompliance 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 and other third parties might be able to enter the market with similar or identical products or technologies, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to the protection afforded by patents, we rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary know-how and trade secrets in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, suppliers, partners and other third parties. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our proprietary know-how or trade secrets. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation (such as a cybersecurity breach). Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable.

In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. Even if we are successful in protecting the confidentiality of our trade secrets, others may independently develop the same information or technology, or may be able to discern or reverse engineer our proprietary information or technology from public sources of information. Additionally, though our agreements with third parties typically restrict their ability to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us, which could harm our competitive position. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects could be materially harmed.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights to or from third parties or otherwise experience disruptions to our business relationships with our current partners or any future licensors, we could lose license rights that are important to our business.

We have and may in the future from time to time enter into license or collaboration agreements with third parties to advance our research or allow commercialization of therapeutic candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, non-compete, funding, milestone, royalty, sublicensing, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our current partners or any future licensors might conclude that we have materially breached any of our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our therapeutic candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our therapeutic candidates.

Disputes may also arise between us and our current partners or any future licensors regarding intellectual property subject to a license agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor or licensee that are not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our therapeutic candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

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

If we cannot acquire or license rights to use technologies on reasonable terms or at all, we may not be able to commercialize our current or any future products or technologies.

In the future, we may identify third-party intellectual property and technology we may need to license in order to engage in our business, including to develop or commercialize new products or technologies, and the growth of our business may depend in part on our ability to acquire, in-license or use this technology. However, such licenses may not be available to us on acceptable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater development or commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if such licenses are available, we may be required to pay the licensor in return for the use of such licensor's technology, including up-front payments, ongoing maintenance fees, payments based on certain milestones such as development and regulatory events and sales volumes, or royalties. In addition, such licenses may be non-exclusive, which could give our competitors and other third parties access to the same intellectual property licensed to us. Moreover, we could encounter delays in the introduction of products while we attempt to develop alternatives. Failure to obtain any of these licenses on favorable terms could prevent us from commercializing our current and any future therapeutic candidates and technologies. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any therapeutic candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any therapeutic candidates we may develop, one or more of our U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process, although the amount of available extension to any specific patent eligible for patent term extension depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. To the extent we have in-licensed any U.S. patents, we may not have control over the patent term extension process and may rely on our partners to obtain a patent term extension. Moreover, under the agreements pursuant to which we out-license or assign our MZE001 and UNC13A patent portfolios, the applicable licensees have the sole right to apply for patent term extensions with respect to the licensed patents and patent applications. If we or our partners are unable to obtain patent term extension or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may become involved in lawsuits to protect or enforce any patents we may own or in-license in the future, which could be expensive, time consuming and unsuccessful and any patents we may own or in-license in the future covering our therapeutic candidates could be found invalid or unenforceable if challenged in courts or patents offices.

Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other claims in order to enforce our intellectual property rights, which can be expensive and time-consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Our ability to enforce our patents or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a third party's product or service.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In such a proceeding, a court may decide that an asserted patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the asserted patent or other intellectual property right does not cover the third-party technology in question. An adverse result in any litigation or defense proceedings could put one or more asserted patents at risk of being invalidated or interpreted narrowly and could put related patent applications at risk of not issuing.

If we were to initiate legal proceedings against a third party to enforce a patent we may own or in-license in the future covering one or more of our therapeutic candidates, the defendant could counterclaim that the patent covering our therapeutic candidate is invalid and/or unenforceable. In patent litigation in the United States or elsewhere, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of subject matter eligibility, lack of novelty, obviousness, lack of adequate written description or non-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 any other applicable patent office, or made a misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as reexaminations, *inter partes* review or post-grant review, or oppositions or similar proceedings in foreign patent offices, in parallel with litigation or even outside the context of litigation. Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our therapeutic candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future therapeutic candidates. Such a loss of patent protection would have a material adverse impact on our business.

In addition, interference, derivation or other 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 current or future patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors or other third parties gain access to the same technology.

Our defense of litigation or interference, derivation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. 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. Any of the foregoing could have a material adverse effect on our financial condition, results of operations and prospects.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. We may design or create new trademarks and apply to register them, but our trademark applications may not be approved in the United States or any other relevant jurisdiction. Our trademarks and trade names may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Competitors or other parties in our industry may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, third parties may infringe our trademarks and we may not have adequate resources to enforce our trademark rights. If we attempt to enforce our trademarks and 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. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential commercial or competitive threats.

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

- others may be able to make products similar to any therapeutic candidates we may develop or utilize similar technologies that are not covered by the claims of patents that we may license or may own in the future;
- we, or any current or future partners, might not have been the first to make the inventions covered by an issued patent or pending patent application that we may license or own in the future;
- we, or any current or future partners, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property and proprietary rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate any patent we may own or license in the future;
- issued patents that we may hold rights to in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have intellectual property rights and then use the information learned from such activities to develop competitive products for sale in our commercial markets;
- we may not develop technologies or therapeutic candidates that are patentable;

- the patents or pending or future patent applications of others, if issued, may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

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

Risks related to our common stock

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

The market price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are outside of our control. The market price for our common stock may be influenced by many factors, including the other risks described in this "Risk Factors" section and the following:

- results of preclinical studies or clinical trials by us or those of our competitors or by existing or future
- the timing and enrollment status of our clinical trials;
- the use and adequacy of our cash reserves;
- changes in the development status of our therapeutic candidates, including variations in the level of expense related to the development of our programs or funding support by us or by existing or future partners;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our business, or uncertainty with respect to such regulatory or legal developments;
- the success of competitive products or technologies;
- introductions and announcements of new therapeutic candidates by us, our existing or future collaboration partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our therapeutic candidates, preclinical studies, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or therapeutic candidates;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- announced or completed significant acquisitions, strategic collaborations, joint ventures, spin-outs or capital commitments by us or our competitors;
- developments or disputes concerning our intellectual property and proprietary rights;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of shares of our common stock by us, insiders or our stockholders;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the concentrated ownership of our common stock;

- changes in accounting principles;
- natural disasters, terrorist acts, acts of war and other calamities;
- political instability, including the occurrence of a temporary federal government shutdown;
- the impact of geopolitical tensions and ongoing regional military conflicts;
- a severe or prolonged economic downturn; and
- general economic and geopolitical conditions, including fluctuating interest and tariff rates, the impact of significant political, trade and regulatory developments, disruptions in the capital and credit markets, market volatility and inflation.

We may, from time to time, elect to sell securities in a public offering or private placement. For example, in September 2025, we entered into a securities purchase agreement with certain investors, pursuant to which we issued and sold in a private placement an aggregate of 4,000,002 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 5,231,090 shares of our common stock. We subsequently registered the common stock (including the shares of common stock issuable upon exercise of the pre-funded warrants) under the Securities Act for resale on Form S-1, such that these shares may now be sold by the purchasers in the public market at any time. In April, 2026, we completed an underwritten registered offering pursuant to which we issued and sold an aggregate of 5,540,000 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 850,000 shares of our common stock. As of June 30, 2026, there were 5,181,090 shares of our common stock subject to outstanding pre-funded warrants, with an exercise price of $0.001 per share. To the extent any of these warrants are exercised, the shares underlying these warrants may be immediately sold in the public market. These sales, or the perception in the market that we or holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. Furthermore, the trading price of our common stock may be adversely affected by third parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and our resources, which could harm our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our company, our common stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our current or future clinical trials, preclinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of February 28, 2026, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 52% of our voting stock. As a result, these stockholders, if acting together, will continue to have influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

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

We are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended, or the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related-party transaction disclosures. 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 due to error or fraud may occur and not be detected.

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

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board of directors;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, or DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: 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 pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated certificate of incorporation provides that the federal district courts of the United States is, to the fullest extent permitted by law, the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, directors, officers, other employees, agents, and the underwriters to any offering giving rise to such complaint, and any other professional person or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

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

General risk factors

We incur increased costs as a result of operating as a public company, and our management must devote substantial time to compliance matters and corporate governance practices.

As a public company, and particularly after we are no longer an EGC, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market, LLC, or Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, like us, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance matters. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. For example, as a public company, it is 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 sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur in the future to respond to these requirements. These requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are an "EGC" and we cannot be certain if the reduced reporting requirements applicable to EGCs will make our common stock less attractive to investors.

We are an "EGC" as defined in the JOBS Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including (i) not being required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our Annual Reports on Form 10-K and our other periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an EGC, we are only required to provide two years of audited financial statements and two years of selected financial data in our Annual Reports on Form 10-K.

We could be an EGC for up to five fiscal years following the completion of our initial public offering; *provided*, *however*, certain circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700 million, if we have total annual gross revenue of $1.235 billion or more, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "EGC" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-EGCs and the date on which we will adopt the recently issued accounting standard.

On December 31, 2025, we determined that we will no longer be a smaller reporting company, beginning with our first quarterly report for the quarter ending March 31, 2026. However, because we remain an EGC, we may continue to rely on the same exemptions from certain disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and the option to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K. We cannot predict if investors will find our common stock less attractive if we choose to 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 share price may be more volatile.

We may become subject to litigation from time to time, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq-listed and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. We may also become subject to intellectual property, commercial or other litigation based on our statements, claims, actions, or inactions, among other things. Litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Unstable market and economic conditions and adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or nonperformance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, and its financial condition and results of operations.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of tariffs, inflation, a potential recession, uncertainty with respect to federal policy, regulations and employment, including those affecting healthcare regulatory bodies such HHS, CDC and FDA, among others, military conflict, terrorism or other geopolitical events. Sanctions or tariffs imposed by the United States and other countries in response to such matters may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. The closure of any additional national or regional commercial banks could lead to further economic instability. Although The Department of the Treasury, the Federal Reserve and the FDIC have taken steps to mitigate these risks, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may still occur in the future.

Although we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. Inflation and fluctuating interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates.

In addition, if any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with any financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, or regulations could be enacted at any time, which may adversely affect our business, financial condition, results of operations and prospects. Further, existing tax laws, statutes, rules, or regulations could be interpreted, changed, modified or applied adversely to us. Future changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. For example, for our 2022 to 2024 tax years, applicable law requires taxpayers to capitalize and amortize certain research and development expenditures over five years if incurred in the United States and fifteen years if incurred in foreign jurisdictions, rather than deducting them concurrently. Beginning with our 2025 tax year, tax legislation has restored immediate deductibility of domestic expenditures, while foreign expenditures will continue to be capitalized and amortized over a 15-year period.

If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal controls over financial reporting beginning with this Annual Report on Form 10-K. When we lose our status as an "EGC" and become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal controls over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with Section 404, we must document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we have dedicated significant internal resources, have engaged outside consultants as needed, and have adopted a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) take steps to improve control processes as appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. This process is time-consuming, costly and complicated.

We believe that any 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. 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, 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.

We, or the third parties upon whom we depend, may be adversely affected by earthquakes, fires, power shortages or other natural disasters our business continuity and disaster recovery plans may not provide adequate protection or coverage.

Our current operations are primarily located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, epidemic, power shortage, telecommunication failure or other natural or man-made accident or incident that results in our being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our therapeutic candidates or interruption of our business operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Our disaster recovery and business continuity plans may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition, results of operation and prospects. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident, incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any such business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Use of Initial Public Offering Proceeds.

On January 30, 2025, our registration statement on Form S-1 (File No 333-284164) relating to our initial public offering of common stock was declared effective by the U.S. Securities and Exchange Commission, or the SEC. Upon the closing of the initial public offering on February 3, 2025, we issued 8,750,000 shares of common stock at a public offering price of $16.00 per share, resulting in net proceeds of approximately $127.8 million, after deducting underwriting discounts, commissions and other payable offering expenses of approximately $12.2 million. J.P. Morgan Securities LLC, TD Securities (USA) LLC, Leerink Partners LLC and Guggenheim Securities, LLC acted as joint book-running managers for the offering. None of the expenses associated with our initial public offering were paid, directly or indirectly, to any of our directors or officers, any persons owning 10% or more of any class of equity securities, or to any of our affiliates.

There has been no material change in the planned use of proceeds from the initial public offering as described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on January 31, 2025.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the three months ended June 30, 2026, the following directors and/or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” in each case as defined in Item 408 of Regulation S-K.

			Character of Trading Arrangement				
Name and Title	**Action Taken**	**Date of Action**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Nature of Trading**	**Aggregate Number of Securities**	**Duration of Trading Arrangement[1]**
Amy Bachrodt, SVP, Finance[2]	Terminated	April 28, 2026	X		Sale	56,000	12/29/2025-12/31/2026

*Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
**"Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.
1 The trading arrangement may expire on an earlier date if and when all transactions under the arrangement are completed.
2 Amy Bachrodt resigned as SVP, Finance of Maze Therapeutics, Inc. (the “Company”), effective June 1, 2026.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit number	Description of document	Incorporated by Reference			
		Form	File No.	Number	Filing Date
4.1	Form of Pre-Funded Warrant.	8-K	001-42490	4.1	4/22/2026
10.1	Non-Employee Director Compensation Policy, as amended June 1, 2026.				Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith
32.1*	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Filed herewith
32.2*	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Filed herewith
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.				Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				Filed herewith
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101				Filed herewith

* This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

MAZE THERAPEUTICS, INC.

Date: August 11, 2026

By: /s/ Jason Coloma
Jason Coloma
Chief Executive Officer
(Principal Executive Officer)

MAZE THERAPEUTICS, INC.

Date: August 11, 2026

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

MAZE THERAPEUTICS, INC. ("*Company*")
Non-Employee Director Compensation Policy

Effective January 30 2025
Amended June 1, 2026

The Company's Board of Directors (the "***Board***") believes it is in the best interests of the Company and its stockholders to adopt a compensation program for non-employee directors as set forth herein (the "***Non-Employee Director Compensation Policy***" or the "***Policy***") to provide for an annual cash retainer and certain equity awards in consideration of each non-employee director's service on the Board and any committees thereof. This Policy may be amended or terminated at any time in the sole discretion of the Board.

Cash Compensation

Cash compensation payable to each non-employee director shall consist of the following annual fees, which shall be paid quarterly in arrears and shall be pro-rated for partial quarters served, including for the initial quarter in which this Policy is adopted:

- General Board Service Fee: $40,000
- Board Chair Fee (in addition to General Board Service Fee): $30,000
- Committee Chair Service Fee (in addition to General Board Service Fee; in lieu of Non-Chair Committee Member Service Fee set forth below):
    - Audit Committee chair: $20,000
    - Compensation Committee chair: $15,000
    - Nominating and Governance Committee chair: $10,000
    - Research and Development Committee chair: $15,000
- Non-Chair Committee Member Service Fee (in addition to General Board Service Fee; in lieu of Committee Chair Service Fee set forth above):
    - Audit Committee member: $10,000
    - Compensation Committee member: $7,500
    - Nominating and Governance Committee member: $5,000
    - Research and Development Committee member: $7,500

Equity Compensation – Initial Award

Upon election or appointment as a member of the Board, each non-employee director shall be granted an option (an, "***Option***") to purchase the lesser of (i) Thirty-Six Thousand (36,000) shares of Company common stock ("***Common Stock***") or (ii) such number of shares of Common Stock resulting in such Option having a grant date fair value (as determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("***ASC 718***")) equal to $750,000, in either case under the Company's 2025 Equity Incentive Plan or any applicable successor thereto (such award, the "***Initial Award***" and such plan, the "***Equity Plan***") and be evidenced by a stock option agreement (the "***Option Agreement***").

The Initial Award will be granted on the date of the non-employee director's appointment to the Board (the "***Initial Award Grant Date***") with an exercise price equal to the fair market value of Common Stock on the Initial Award Grant Date, as determined pursuant to the terms of the Equity Plan.

The Initial Award shall vest as to 1/36th of the total number of shares subject to the Initial Award on each monthly anniversary of the Initial Award Grant Date such that the Initial Award shall be fully vested on the third annual anniversary of the Initial Award Grant Date, in each case, so long as the non-employee director continues to provide Services (as defined in the Equity Plan) to the Company through such date. If a non-employee director's Service ends on the date of vesting, then the vesting shall be deemed to have occurred.

The Initial Award shall accelerate in full upon the consummation of a Corporate Transaction (as defined in the Equity Plan) if the applicable non-employee director is then in Service to the Company.

Equity Compensation – Annual Award

On the date of each annual meeting of the Company's stockholders, each non-employee director who is serving on the Board immediately prior to (provided that the non-employee director must have initially joined the Board by no later than January 1st prior to the Company's annual stockholder meeting), and will continue to serve on the Board following, the annual meeting shall be granted an Option under the Equity Plan to purchase the lesser of (i) Eighteen Thousand (18,000) shares of Company Common Stock or (ii) such number of shares of Common Stock resulting in such Option having a grant date fair value (as determined in accordance with ASC 718) equal to $375,000, in either case under the Equity Plan (such award, the "***Annual Award***") and be evidenced by an Option Agreement.

The Annual Award will automatically be granted on the date of the annual meeting of the Company's stockholders (the "***Annual Award Grant Date***") and will have an exercise price with an exercise price equal to the fair market value of Common Stock on the Annual Award Grant Date, as determined pursuant to the terms of the Equity Plan.

The Annual Award shall fully vest on the earlier of (i) the one-year anniversary of the Annual Award Grant Date and (ii) the next annual meeting of the Company's stockholders, so long as the non-employee director continues to provide Services to the Company through the applicable vesting date. If a non-employee director's Service ends on the date of vesting, then the vesting shall be deemed to have occurred.

The Annual Award shall accelerate in full upon the consummation of a Corporate Transaction (as defined in the Equity Plan) if the applicable non-employee director is then in Service to the Company.

Compensation Limit

Notwithstanding any other provision of this Policy to the contrary, in no event will the total amount of annual compensation payable to any non-employee director following the effective date of this Policy exceed the limits set forth in Section 12.2 of the Equity Plan.

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Jason Coloma, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Maze Therapeutics Inc.;

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

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

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2026

By: /s/ Jason Coloma

Jason Coloma, Ph.D.

Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Misbah Tahir, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Maze Therapeutics Inc.;

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

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

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2026

By: /s/ Misbah Tahir

Misbah Tahir

Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

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

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), I, Jason Coloma, Ph.D., Chief Executive Officer of Maze Therapeutics Inc. (the "Company"), hereby certify that:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 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.

Date: August 11, 2026

By: /s/ Jason Coloma
Jason Coloma, Ph.D.
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

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

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), I, Misbah Tahir, Chief Financial Officer of Maze Therapeutics Inc. (the "Company"), hereby certify that:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2026, to which this Certification is attached as Exhibit 32.2 (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.

Date: August 11, 2026

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer (Principal Financial and Accounting Officer)