UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from to

Commission File Number: 001-40335

Biomea Fusion, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-2520134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1599 Industrial Road	
San Carlos, California	**94070**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 980-9099

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

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

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

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

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

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

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

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

As of November 6, 2026, the registrant had 72,678,080 shares of common stock, $0.0001 par value per share, outstanding.

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Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash, cash equivalents and restricted cash to fund our future operating expenses and capital expenditure requirements;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to continue as a going concern;
- our ability to maintain compliance with The Nasdaq Stock Market LLC's (Nasdaq's) continued listing requirements, including the minimum bid price and the risk that our common stock could be delisted from Nasdaq;
- our anticipated use of our existing cash, cash equivalents and restricted cash;
- the implementation of our strategic plans for our business and product candidates;
- the initiation, timing, progress and results of our research and development programs, nonclinical studies, clinical trials and investigational new drug (IND) applications and other regulatory submissions;
- our ability to develop our product candidates for the treatment of type 1 and type 2 diabetes, obesity and other metabolic diseases;
- the timing, progress and focus of our ongoing and future clinical trials, and the reporting of data from those trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
- our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved;
- our estimates of the patient populations addressable by our product candidates, if approved, and the number of participants that will enroll in our ongoing and planned clinical trials;
- the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
- our ability to enter into strategic partnerships with collaborators with development, regulatory and commercialization expertise and the expected benefits of any such potential future strategic collaborations;
- the success of competing therapies that are or may become available;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our ability to obtain sufficient funding or enter into strategic collaborations for the advancement of certain of our product candidate programs;
- our plan to rely on third parties to conduct and support nonclinical and clinical development;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- the impact of any global health emergencies or other related disruptions on our business;

- the impact of new laws and regulations, amendments to existing laws and regulations, or changes in government agencies, in the United States and foreign countries;
- unfavorable macroeconomic conditions or market volatility resulting from global economic conditions or geopolitical developments, including supply chain issues, inflationary pressures, market volatility, international tariffs, trade protection measures, economic sanctions, economic slowdowns or recessions, acts of war and civil and political unrest; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act).

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, 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 at all. You should refer to the section titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements.

Biomea Fusion, Inc., the Biomea logo and our other registered or common law trademarks, trade names or service marks appearing in this Quarterly Report on Form 10-Q are owned by us. This Quarterly Report on Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q, including logos, artwork and other visual displays, generally appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Summary Risk Factors

The following is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address every aspect of our risk factors, all of the risks that we face, or other factors not presently known to us or that we currently believe are immaterial. Additional discussion of the risks summarized in these summary risk factors, and other risks that we face, can be found under the heading "Risk Factors" in this Quarterly Report on Form 10-Q and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the U.S. Securities and Exchange Commission (SEC), before making investment decisions regarding our common stock.

- We have a limited operating history, limited experience in conducting clinical trials, have not completed the clinical development of any product candidates, have no products approved for commercial sale, and have not generated any revenue, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- There is substantial doubt about our ability to continue as a going concern, and we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs or future commercialization efforts.
- Our development activities are focused on the development of novel small-molecule therapies to treat patients with diabetes and obesity, and the approach we are taking to develop such product candidates is novel, may never lead to marketable products and may not ultimately represent a significant or viable market.
- We are early in our development efforts and are substantially dependent on our product candidates, icovamenib (formerly BMF-219) and BMF-650. If we are unable to advance icovamenib, BMF-650 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize icovamenib, BMF-650 or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.
- Nonclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our nonclinical and clinical programs may experience delays or may never be initiated or completed, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.
- The results of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (FDA) or other comparable foreign regulatory authorities. Successful nonclinical studies and clinical trials cannot provide assurance of successful commercialization.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- Adverse global economic conditions and geopolitical developments, including supply chain issues, tariffs, inflationary pressures, trade protection measures, economic sanctions, economic slowdowns or recessions, acts of war and other global conflicts, and civil and political unrest, could materially adversely impact our business, results of operations, and financial condition, including our nonclinical studies and clinical trials.
- The price of our stock has been and is likely to continue to be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.
- Our stockholders have experienced, and may continue to experience, substantial dilution from future sales and issuances of our capital stock, including upon the exercise of outstanding warrants issued in our underwritten public offerings completed in June 2025 and October 2025.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Biomea Fusion, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 26,403	$ 55,812
Prepaid expenses and other current assets	890	2,238
Restricted cash, current	369	—
Total current assets	27,662	58,050
Property and equipment, net	37	153
Restricted cash, non-current	—	369
Other assets, non-current	398	—
Total assets	$ 28,097	$ 58,572
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,260	$ 3,233
Accrued expenses and other current liabilities	9,005	6,407
Operating lease liabilities, current	506	1,461
Total current liabilities	12,771	11,101
Operating lease liabilities, non-current	—	128
Warrant liability, non-current	7,740	17,791
Total liabilities	20,511	29,020
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 0 shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 72,678,080 and 72,299,440 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	7	7
Additional paid-in capital	483,553	478,593
Accumulated deficit	(475,974)	(449,048)
Total stockholders' equity	7,586	29,552
Total liabilities and stockholders' equity	$ 28,097	$ 58,572

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

Biomea Fusion, Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 8,531	$ 14,401	$ 26,793	$ 53,864
General and administrative	4,432	4,199	11,710	15,724
Impairment of long-lived assets	—	2,205	—	2,205
Total operating expenses	12,963	20,805	38,503	71,793
Loss from operations	(12,963)	(20,805)	(38,503)	(71,793)
Change in fair value of common warrant liability	6,513	3,872	10,051	4,099
Gain on sale of property and equipment	—	—	510	—
Interest and other income, net	267	526	1,016	1,285
Net and comprehensive loss	$ (6,183)	$ (16,407)	$ (26,926)	$ (66,409)
Net loss per common share, basic and diluted	$ (0.09)	$ (0.27)	$ (0.37)	$ (1.45)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	72,591,786	59,848,325	72,418,224	45,787,018

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

Biomea Fusion, Inc.
Condensed Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2025	72,299,440	$ 7	$ 478,593	$ (449,048)	$ 29,552
Stock-based compensation expense	—	—	1,582	—	1,582
Net loss	—	—	—	(12,415)	(12,415)
Balance at March 31, 2026	72,299,440	$ 7	$ 480,175	$ (461,463)	$ 18,719
Purchases under employee stock purchase plan	184,412	—	159	—	159
Stock-based compensation expense	—	—	1,587	—	1,587
Net loss	—	—	—	(8,328)	(8,328)
Balance at June 30, 2026	72,483,852	$ 7	$ 481,921	$ (469,791)	$ 12,137
Issuance of common shares upon restricted stock units vesting	186,128	—	—	—	—
Exercise of stock options	8,100	—	12	—	12
Stock-based compensation expense	—	—	1,620	—	1,620
Net loss	—	—	—	(6,183)	(6,183)
Balance at September 30, 2026	72,678,080	$ 7	$ 483,553	$ (475,974)	$ 7,586

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2024	36,310,713	$ 4	$ 438,820	$ (387,251)	$ 51,573
Issuances of common stock under at the market equity offering program, net of issuance costs of $5	1,261,537	—	3,257	—	3,257
Stock-based compensation expense	—	—	3,169	—	3,169
Net loss	—	—	—	(29,262)	(29,262)
Balance at March 31, 2025	37,572,250	$ 4	$ 445,246	$ (416,513)	$ 28,737
Purchases under employee stock purchase plan	95,421	—	117	—	117
Issuances of common stock under at the market equity offering program, net of issuance costs of $129	1,009,585	—	1,651	—	1,651
Issuance of common stock and pre-funded warrants under the public offering, net of issuance costs of $2,815	19,450,000	2	15,170	—	15,172
Stock-based compensation expense	—	—	2,573	—	2,573
Net loss	—	—	—	(20,740)	(20,740)
Balance at June 30, 2025	58,127,256	$ 6	$ 464,757	$ (437,253)	$ 27,510
Issuances of common stock under the public offering, net of issuance costs of $186	1,381,262	—	2,576	—	2,576
Stock-based compensation expense	—	—	1,940	—	1,940
Net loss	—	—	—	(16,407)	(16,407)
Balance at September 30, 2025	59,508,518	$ 6	$ 469,273	$ (453,660)	$ 15,619

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

Biomea Fusion, Inc.
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Operating Activities		
Net loss	$ (26,926)	$ (66,409)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	76	1,362
Non-cash operating lease expense	—	1,674
Stock-based compensation expense	4,789	7,682
Change in fair value of warrant liability	(10,051)	(4,099)
Impairment of property and equipment	—	2,205
Gain on sale of property and equipment	(510)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,348	7,255
Other assets	(398)	619
Accounts payable	27	(6,531)
Accrued expenses and other current liabilities	2,598	1,708
Operating lease liabilities	(1,083)	(1,895)
Net cash used in operating activities	(30,130)	(56,429)
Investing Activities		
Proceeds from sale of property and equipment	550	—
Net cash provided by investing activities	550	—
Financing Activities		
Proceeds from issuances of common stock under at the market equity offering program	—	5,032
Proceeds from issuance of common stock, common warrants and pre-funded warrants from public offering	—	40,396
Proceeds from stock option exercise and purchases under the employee stock purchase plan	171	117
Payments of financing costs	—	(753)
Net cash provided by financing activities	171	44,792
Net decrease in cash, cash equivalents, and restricted cash	(29,409)	(11,637)
Cash, cash equivalents, and restricted cash at the beginning of the period	56,181	58,648
Cash, cash equivalents, and restricted cash at the end of the period	$ 26,772	$ 47,011
Non-cash financing and investing activities:		
Financing costs included in accounts payable and accrued liabilities	$ —	$ 11
Reconciliation of cash and cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 26,403	$ 46,642
Restricted cash	369	369
Total cash and cash equivalents, and restricted cash	$ 26,772	$ 47,011

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

Biomea Fusion, Inc.
Notes to Unaudited Condensed Financial Statements

Note 1. Organization

Organization

Biomea Fusion, Inc., (the Company), was established in the state of Delaware in August 2017 as Biomea Fusion, LLC. In December 2020, all outstanding membership interests in Biomea Fusion, LLC were converted into equity interests in the Company. The capitalization information included in these unaudited condensed financial statements is consistently presented as if it is that of Biomea Fusion, Inc., even during the prior period when investors held their equity interests in Biomea Fusion, LLC.

The Company was founded with the goal of creating targeted treatments built through expertise in chemistry and a deep understanding of metabolic biology. The Company is a clinical-stage diabetes and obesity medicines company focused on the development of oral, small molecule drugs to treat and improve the lives of patients with diabetes, obesity and other metabolic diseases.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and applicable rules and regulations of the SEC regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly, the balance sheet as of December 31, 2025 has been derived from the audited financial statements at that date but does not include all of the information required by GAAP for complete financial statements. These unaudited condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments which are necessary for a fair statement of the Company's financial information. The unaudited interim results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other interim period or for any other future year.

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2025, included in the Company's Annual Report on Form 10-K filed with the SEC on March 24, 2026.

Reclassification of Prior Period Presentation

Certain reclassifications have been made to prior period balances in order to conform with the current period's presentation, reclassifying $4.1 million from Interest and other income, net to Change in fair value of common warrant liability in the condensed statement of operations. The reclassification had no effect on the condensed balance sheet, condensed statement of stockholders' equity and condensed statement of cash flows.

Liquidity and Capital Resources

The Company has incurred net operating losses (NOLs) and negative cash flows from operations since its inception and had an accumulated deficit of $476.0 million at September 30, 2026. As of September 30, 2026, the Company had cash, cash equivalents, and restricted cash of $26.8 million. Management believes that the existing financial resources are not sufficient to continue operating activities for at least twelve months past the issuance date of these unaudited condensed financial statements. The Company's ability to continue as a going concern will require the Company to raise additional capital to fund the Company's operations through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. There can be no assurance that additional financing will be available to the Company or that such financing, if available, will be available on terms acceptable to the Company. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern.

The Company has historically financed its operations primarily through the sale of common stock and warrants and the issuance of unsecured promissory notes. To date, none of the Company's product candidates have been approved for commercial sale, and the Company has not generated any revenue since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company continues clinical development activities for its lead product candidate and advances the nonclinical and clinical development of other product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed below. There can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

Note 2. Summary of Significant Accounting Policies

There have been no significant changes to the significant accounting policies during the nine months ended September 30, 2026, as compared to those included in the Company's Annual Report on Form 10-K filed with the SEC on March 24, 2026.

Recent Accounting Pronouncements - Not Yet Adopted

In November 2024, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03), which requires disaggregated information about certain income statement expense line items on an annual and interim basis. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and can be applied prospectively or retrospectively. The Company is evaluating the impact of the adoption of this standard on the Company's financial statements and related disclosures.

Note 3. Fair Value Measurement

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The following tables set forth the fair value of the Company's financial assets, which consist of marketable securities measured and recognized at fair value (in thousands):

		September 30, 2026			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets included in cash and cash equivalents:					
Money market funds	Level 1	$ 25,659	$ —	$ —	$ 25,659
Total		25,659	—	—	25,659
Liabilities:					
Warrant liability	Level 3	7,740	—	—	7,740
Total		$ 7,740	$ —	$ —	$ 7,740

		December 31, 2025			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets included in cash and cash equivalents:					
Money market funds	Level 1	$ 55,030	$ —	$ —	$ 55,030
Total		55,030	—	—	55,030
Liabilities:					
Warrant liability	Level 3	17,791	—	—	17,791
Total		$ 17,791	$ —	$ —	$ 17,791

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Levels 1, 2 and 3 during the three and nine months ended September 30, 2026 and 2025. There have been no realized or unrealized gains or losses recognized for the periods presented.

There were no investments as of September 30, 2026 and December 31, 2025, as such, no allowance for credit losses has been recognized as of September 30, 2026. During the three and nine months ended September 30, 2026 and 2025, the Company did not recognize any impairment losses related to investments.

The warrant liability in the table above consisted of the fair value of the Common Warrants (see Note 5) and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The following table provides a full roll forward of the aggregate fair value of the warrant liability categorized within Level 3 inputs (in thousands):

	Warrant Liability
Balance at December 31, 2025	$ 17,791
Issuance of common warrants	—
Change in fair value	(10,051)
Balance at September 30, 2026	$ 7,740

Note 4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Laboratory equipment	$ —	$ 102
Computer equipment	146	146
Furniture and fixtures	416	432
Leasehold improvements	106	482
Total property and equipment, gross	668	1,162
Less: accumulated depreciation	(631)	(1,009)
Total property and equipment, net	$ 37	$ 153

Depreciation expense for the three and nine months ended September 30, 2026 was less than $0.1 million. Depreciation expense for the three and nine months ended September 30, 2025 was $0.4 million and $1.4 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued research and development materials and services	$ 6,208	$ 3,163
Accrued personnel expenses	2,175	2,958
Accrued professional services	478	117
Other	144	169
Total accrued expenses and other current liabilities	$ 9,005	$ 6,407

Note 5. Capital Structure

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue up to 300,000,000 shares of common stock with a par value of $0.0001 per share and 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

Common stockholders are entitled to dividends when and if declared by the Company's Board of Directors (the Board) and after any preferred share dividends are fully paid. The holder of each share of common stock is entitled to one vote. As of September 30, 2026, no dividends have been declared.

Public Offerings

In April 2023, pursuant to a registration statement on Form S-3, the Company issued and sold 5,750,000 shares of common stock at a public offering price of $30.00 per share in an underwritten public offering. The net proceeds to the Company from the offering were approximately $161.8 million, after deducting underwriting discounts and commissions and offering costs of approximately $11.0 million.

In June 2025, the Company completed an underwritten public offering transaction in which it issued and sold 19,450,000 shares of common stock at an offering price of $2.00 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 550,000 shares of common stock at an offering price of $1.9999 per share and accompanying common warrants to purchase up to 23,000,000 shares of common stock at a per share exercise price of $2.50. The net proceeds to the Company from the offering were approximately $37.2 million, after deducting underwriting discounts and commissions and offering costs of approximately $2.8 million.

In July 2025, in connection with the completed underwritten public offering, the underwriters partially exercised their over-allotment option to purchase an additional 1,381,262 shares of common stock at an offering price of $2.00 per share. The net proceeds from the offering pursuant to the over-allotment option were approximately $2.6 million, after deducting underwriting discounts and commissions and offering costs of approximately $0.2 million.

In October 2025, the Company completed an underwritten public offering transaction in which it issued and sold 11,195,121 shares of common stock at an offering price of $2.05 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 1,000,000 shares of common stock at an offering price of $2.0499 per share and accompanying common warrants to

purchase up to 12,195,121 shares of common stock at a per share exercise price of $2.50. The underwriters partially exercised their overallotment option to purchase 1,829,268 shares of common stock. The net proceeds to the Company from the offering were approximately $23.1 million, after deducting underwriting discounts and commissions and offering costs of approximately $1.9 million.

The Company concluded that the common warrants do not meet the equity contract scope exception. The liability associated with the common warrants is recorded as warrant liability in the condensed balance sheet as of September 30, 2026.

The valuation of the common warrants is adjusted to fair value (Level 3) at each subsequent balance sheet date until the common warrants are settled or expired. To this date, due primarily to fluctuations in the Company's common stock price between the issuance date and September 30, 2026, the warrant liability was revalued at $7.7 million as of September 30, 2026. The change in fair value of $10.1 million has been recorded as change in fair value of common warrant liability.

The Company calculated the fair value of common warrants using the Black-Scholes option pricing model with the following inputs:

	June 2025 Underwritten Public Offering	
	June 20, 2025 (issuance)	September 30, 2026 (period end)
Common stock price	$ 1.81	$ 1.33
Expected dividend yield	—%	—%
Expected term (years)	1.5	0.2
Risk-free interest rate	4.0%	4.2%
Expected volatility	132.9%	74.7%

	October 2025 Underwritten Public Offering	
	October 8, 2025 (issuance)	September 30, 2026 (period end)
Common stock price	$ 1.68	$ 1.33
Expected dividend yield	—%	—%
Expected term (years)	3.0	2.0
Risk-free interest rate	3.6%	4.9%
Expected volatility	121.6%	101.5%

Common Stock Warrants

As of September 30, 2026, the following warrants to purchase shares of the Company's common stock were issued and outstanding:

Warrant Type	Issue Date	Expiration Date	Exercise Price	Number of Warrants Outstanding
Common warrants	June 20, 2025	December 20, 2026	$ 2.50	23,000,000
Common warrants	October 8, 2025	October 8, 2028	$ 2.50	14,024,389
				37,024,389

There were no warrants exercised during the three and nine months ended September 30, 2026.

ATM Offering Agreement with Piper Sandler & Co.

On November 25, 2022, the Company entered into an equity distribution agreement (the 2022 ATM Agreement) with Piper Sandler & Co. (Piper Sandler), as sales agent, with respect to an ATM offering program (the 2022 ATM Offering Program). Pursuant to the prospectus supplement relating to the Offering (as defined below), dated as of November 25, 2022 (the Prospectus Supplement), the Company may offer and sell, from time to time in its sole discretion, shares of its common stock, par value $0.0001 per share (the Common Stock), having an aggregate offering price of up to $100 million (the Shares) through Piper Sandler (the Offering).

The Offering was registered under the Securities Act of 1933, as amended (the Securities Act), pursuant to the Company's shelf registration statement on Form S-3 (Registration Statement No. 333-267884), as previously filed with the SEC and declared effective on October 14, 2022 (the 2022 Registration Statement). The Company filed a prospectus supplement, dated November 25, 2022, with the SEC that provided for the sale of shares of common stock having an aggregate offering price of up to $100 million in connection with the 2022 ATM Offering Program.

On August 5, 2025, the Company filed a new shelf registration statement on Form S-3 (Registration Statement No. 333-289262), which was declared effective on August 15, 2025 (the 2025 Registration Statement), which replaced the previously filed 2022 Registration Statement. The 2025 Registration Statement included a prospectus, dated August 5, 2025, that provides for the sale of shares of common stock having an aggregate offering price of up to $100 million in connection with the 2022 ATM Offering Program.

The 2022 ATM Agreement contains customary representations, warranties and agreements by us, and customary indemnification and contribution rights and obligations of the parties. The Company agreed to pay Piper Sandler a placement fee of up to 3.0% of the aggregate gross proceeds from the sale. The Company also agreed to reimburse Piper Sandler for certain specified expenses in connection with entering into the 2022 ATM Agreement.

During the nine months ended September 30, 2026, the Company did not receive any proceeds from its 2022 ATM Offering Program and no shares of common stock were issued. During the nine months ended September 30, 2025, the Company had received aggregate proceeds from its 2022 ATM Offering Program of $4.9 million, net of commissions and offering costs, pursuant to the issuance of 2,271,122 shares of its common stock.

Note 6. Stock-Based Compensation

Effective January 1, 2026, the number of shares of common stock available under the 2021 Incentive Award Plan (the 2021 Plan) increased by 3,614,972 shares pursuant to the evergreen provision. As of September 30, 2026, 1,694,848 shares of common stock remained available for issuance under the 2021 Plan.

Effective January 1, 2026, the number of shares of common stock available under the 2021 Employee Stock Purchase Plan (the ESPP) increased by 722,994 shares pursuant to the evergreen provision of the ESPP. As of September 30, 2026, 1,343,590 shares of common stock remained available for issuance under the ESPP.

As of September 30, 2026, 1,879,032 shares of common stock remained available for issuance under the 2023 Inducement Equity Plan as adopted in November 2023.

Repricing

On August 11, 2025 (the Repricing Effective Date), the Company's Board approved a repricing of certain outstanding vested and unvested stock option awards under the 2021 Plan for eligible non-executive employees and certain other service providers (the Repricing Participants). The per share exercise price of eligible stock option awards was reduced to $4.50. To receive the benefit of the repricing, Repricing Participants were required to remain an employee or service provider through the period (the Retention Period) that began on the Repricing Effective Date and ended on September 12, 2025 (the Retention Date). No other changes were made to the terms and conditions of the eligible stock option awards. The stock option repricing impacted approximately 2.6 million shares of common stock subject to stock option awards and affected 48 employees and service providers.

The repricing resulted in a total incremental stock-based compensation expense of $0.4 million, which was calculated using the Black-Scholes option pricing model, of which $0.3 million is associated with vested repriced options as of the Retention Date and was recognized on a straight-line basis over the Retention Period. The remaining $0.1 million of the incremental stock-based compensation expense is associated with unvested repriced options beyond the Retention Period and will be recognized on a straight-line basis over the remaining original vesting periods. For the nine months ended September 30, 2026 and 2025, the Company recognized $0 million and $0.3 million, respectively, of incremental stock-based compensation expense related to the repricing.

Stock-Based Compensation Expense

Total stock-based compensation expense related to the Company’s equity incentive plans and ESPP was recorded in the statements of operations and allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 775	$ 1,075	$ 2,338	$ 4,563
General and administrative	845	865	2,451	3,119
Total stock-based compensation expense	$ 1,620	$ 1,940	$ 4,789	$ 7,682

As of September 30, 2026, there was $11.2 million of total unrecognized stock-based compensation expense which is expected to be recognized over a weighted-average period of 2.7 years.

Stock Options

The following table summarizes the Company's stock option activity:

	Outstanding Options		
	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance, December 31, 2025	8,255,280	$ 4.11	8.0
Granted	5,157,920	1.44	
Exercised	(8,100)	1.49	
Cancelled	(441,644)	2.14	
Balance, September 30, 2026	12,963,456	$ 3.11	8.0
Exercisable, September 30, 2026	5,715,947	$ 4.87	6.6

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2025	892,500	$ 1.53
Issued	—	—
Vested	(186,128)	1.53
Canceled/Forfeited	(157,750)	1.53
Unvested at September 30, 2026	548,622	$ 1.53

Note 7. Commitments and Contingencies

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Management is currently not aware of any legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is not material.

The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

Note 8. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

The following equity instruments were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	September 30,	
	2026	2025
Stock options, issued and outstanding	12,963,456	9,010,875
Estimated shares issuable under the ESPP	147,753	110,144
Restricted stock subject to future vesting	548,622	892,500
Common warrants to purchase common stock	37,024,389	23,000,000
Total	50,684,220	33,013,519

Note 9. Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing small molecule drugs to treat patients with metabolic diseases. The Company's interim chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
External costs:				
Clinical research organization expenses				
COVALENT - 101	$ —	241	$ —	$ 2,168
COVALENT - 102	—	668	—	1,140
COVALENT - 103	(132)	1,146	370	2,744
COVALENT - 111	(18)	1,032	(18)	4,367
COVALENT - 112	(22)	601	(22)	1,414
COVALENT - 211	1,883	—	4,149	—
COVALENT - 212	919	—	2,266	—
GLP - 131	579	255	2,802	255
Other clinical related expenses	1,251	1,396	3,252	4,726
Nonclinical activities related expenses	8	1,191	163	4,741
Expenses related to manufacturing of clinical and research material	399	1,420	1,682	3,689
Other external costs	470	1,429	1,709	5,900
Internal costs:				
Personnel-related expenses (including stock-based compensation)	2,850	3,822	9,373	17,342
Facilities and other allocated expenses	344	1,200	1,067	5,378
Total research and development expenses	$ 8,531	$ 14,401	$ 26,793	$ 53,864

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
External costs	$ 1,959	$ 1,375	$ 4,245	$ 4,923
Internal costs:				
Personnel-related expenses (including stock-based compensation)	2,154	2,517	6,520	9,627
Facilities and other allocated expenses	319	307	945	1,174
Total general and administrative expenses	$ 4,432	$ 4,199	$ 11,710	$ 15,724

Reconciliation of segment loss from operations to net loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Loss from operations of reportable segments	$ (12,963)	$ (20,805)	$ (38,503)	$ (71,793)
Change in fair value of common warrant liability	6,513	3,872	10,051	4,099
Gain on sale of property and equipment	—	—	510	—
Interest and other income, net	267	526	1,016	1,285
Net loss	$ (6,183)	$ (16,407)	$ (26,926)	$ (66,409)

Note 10. Subsequent Events

None.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a clinical-stage diabetes and obesity medicines company focused on the development of novel small molecule therapies to treat and improve the lives of patients with metabolic diseases.

Our lead clinical program's drug candidate, icovamenib, is an orally administered investigational small molecule currently in Phase 2 clinical development for the treatment of type 1 and type 2 diabetes. Nonclinical evidence shows that icovamenib promotes reversible downmodulation of menin, a transcriptional regulator implicated in beta cell biology. Nonclinical data also has shown that icovamenib induced glucose-dependent beta cell proliferation and enhanced insulin production and secretion. Through these proposed mechanisms, icovamenib has the potential to restore beta cell mass and function and thereby improve glycemic control. As a potential beta cell restorative therapy, icovamenib represents a novel treatment approach for individuals living with diabetes. Icovamenib's potential in type 1 and type 2 diabetes as well as its impact in obesity is currently being investigated in three clinical and multiple nonclinical studies. Our nonclinical and clinical data to date support that inhibiting menin via icovamenib has the potential to enable the proliferation, preservation, and reactivation of healthy, functional beta cells capable of producing insulin, thereby leading to long-term glycemic control in patients with type 1 and type 2 diabetes.

In nonclinical studies, the administration of icovamenib has produced a pronounced effect in nonclinical models of diabetes, normalizing glucose levels during treatment and even after drug washout. In October 2025, we reported 52-week results from our Phase II COVALENT-111 trial of icovamenib in type 2 diabetes and most recently in April 2026, we reported topline results from our type 1 diabetes trial (COVALENT-112) of icovamenib in type 1 diabetes. As of September 30, 2026 icovamenib is now being evaluated across two ongoing Phase II clinical trials (COVALENT-211 and COVALENT-212) in type 2 diabetes, with the primary 26-week HbA1c endpoint readout from our Phase II clinical trial (COVALENT-211) expected in the first quarter of 2027, and the corresponding 26-week primary endpoint HbA1c readout from our Phase II clinical trial (COVALENT-212), expected in the second quarter of 2027. Longer-term 52-week secondary endpoint data from both COVALENT-211 and COVALENT-212 are expected subsequently. In June 2026, we announced a collaboration with the University of Leicester as part of the ongoing platform research study titled *Investigating and Optimizing Physical Function with Weight Loss: A Multi-Arm Open Label Adaptive Platform Trial (OPAL)*. This newly activated experimental arm will evaluate the effects of icovamenib in combination with low-dose semaglutide in individuals without type 2 diabetes that are either overweight or obese. The collaborative study is designed to assess if adding icovamenib to semaglutide (a GLP-1 therapy) will enhance the body weight lowering effects of semaglutide while supporting muscular and skeletal health.

In September 2025, we announced that BMF-650, our investigational, next-generation, oral small molecule glucagon-like peptide-1 GLP-1 receptor agonist (GLP-1 RA), received IND-clearance from the FDA. In October 2026, we announced interim, topline results from our ongoing Phase Ib clinical trial for BMF-650. With its unique pharmacokinetic profile, enhanced oral bioavailability, and potential for rapid, one-step dose escalation, we believe BMF-650 has the potential to provide a best-in-class therapeutic option for obesity.

Since commencing operations in 2017, we have devoted substantially all of our efforts and financial resources to conducting research and development activities, including drug discovery and nonclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We have not generated any revenue from product sales and, as a result, we have never been profitable and have incurred net losses since commencement of our operations.

As of September 30, 2026, we had an accumulated deficit of $476.0 million. We incurred net losses of $26.9 million and $66.4 million for the nine months ended September 30, 2026 and 2025, respectively. Based on our current operating plan, we believe that our existing cash and cash equivalents, and restricted cash as of September 30, 2026, without any future financing, will only be sufficient to fund our operations into the second quarter of 2027. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities.

We do not expect to generate revenue from product sales unless and until we obtain regulatory approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. We expect that our expenses will continue to increase for the foreseeable future. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct our ongoing nonclinical studies, our two Phase II clinical trials of icovamenib in type 2 diabetes and our Phase I clinical trial of BMF-650 in obese, otherwise healthy volunteers;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- continue our research and development efforts and submit additional INDs;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

We will need to raise additional capital in the future to fund our operations, including to conduct and complete clinical trials for any product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates. All of our product candidates are novel small molecules and are manufactured in synthetic processes from available or custom synthesized starting materials. The chemistry is scalable and uses commonly available pharmaceutical equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities. In addition, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales.

In April 2021, we completed our initial public offering (IPO) and issued an aggregate of 9,000,000 shares of our common stock at a price of $17.00 per share. Subsequent to the close, an additional 823,532 shares were issued in connection with the partial exercise by the underwriters of their option to purchase additional shares of common stock. In addition, immediately prior to the closing of the IPO, all outstanding shares of our convertible preferred stock automatically converted into 7,064,925 shares of common stock. Proceeds from the IPO, net of underwriting discounts and commissions and offering costs were $152.8 million. On April 3, 2023, we issued and sold 5,750,000 shares of common stock, which included 750,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $30.00 per share in an underwritten public offering pursuant to a shelf registration on Form S-3. Our net proceeds from the offering were $161.8 million, after deducting underwriting discounts and commissions and offering costs of $10.7 million. During the twelve months ended December 31, 2025, we issued 2,271,122 shares of our common stock for aggregate proceeds of $4.9 million, net of commissions and offering costs from our 2022 ATM Program. We did not issue any shares of common stock or receive any proceeds under our 2022 ATM Program during the nine months ended September 30, 2026.

In June 2025, we issued and sold 19,450,000 shares of common stock at an offering price of $2.00 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 550,000 shares of common stock at an offering price of $1.9999 per share, and accompanying common warrants to purchase up to 23,000,000 shares of common stock at a per share exercise price of $2.50. In July 2025, in connection with the June 2025 underwritten public offering, the underwriters partially exercised their over-allotment option to purchase an additional 1,381,262 shares of common stock at an offering price of $2.00 per share. The aggregate gross proceeds from the offering, including the proceeds from the underwriters' over-allotment option, were approximately $42.8 million, before deducting underwriting discounts and commissions and offering costs.

In October 2025, we issued and sold 11,195,121 shares of common stock at an offering price of $2.05 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 1,000,000 shares of common stock at an offering price of $2.0499 per share and accompanying common warrants to purchase up to 14,024,389 shares of common stock at a per share exercise price of $2.50, which included the underwriters' partial exercise of their over-allotment option to purchase additional common warrants. The aggregate gross proceeds from the offering, including the proceeds from the underwriters' over-allotment option, were approximately $25.0 million, before deducting underwriting discounts and commissions and offering costs.

Components of Operating Results

Revenue

To date, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future.

Operating Expenses

Research and Development

Our research and development expenses consist primarily of external and internal costs incurred in connection with the research and development of our research programs and product candidates.

External costs include:

- expenses incurred under agreements with third-party contract manufacturing organizations (CMOs), contract research organizations (CROs), research and development service providers, academic research institutions and consulting costs; and
- laboratory expenses, including supplies and services.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel in research and product development roles; and
- facilities and other allocated expenses, including expenses for rent and facilities maintenance, and depreciation.

We expense research and development costs in the periods in which they are incurred. Non-refundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. We track direct costs by stage of program, clinical or nonclinical. However, we do not track indirect costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

We expect our research and development expenses to increase substantially during the next few years as we seek to initiate and complete clinical trials, pursue regulatory approval of icovamenib and advance BMF-650 through nonclinical and clinical development. Predicting the timing or the final cost to complete our clinical program or validation of our manufacturing and supply processes is difficult and delays may occur because of many factors. The process of conducting the necessary nonclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that our product candidates continue to advance into clinical trials, as well as advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable.

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

- the scope, rate of progress, expense and results of our ongoing clinical trials, including our ongoing Phase II clinical trial of icovamenib in type 2 diabetes and our Phase I clinical trial for BMF-650, as well as any future nonclinical development and clinical trials of our product candidates, and other research and development activities we may conduct;
- uncertainties in clinical trial design and the interpretation of clinical trial data;
- per participant trial costs;
- the duration, scope and number of trials required for approval;
- the number of sites included in the trials;
- the number of participants who participate in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible participants;
- the drop-out or discontinuation rates of participants;
- the safety and efficacy profiles of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and any comparable regulatory authorities outside the United States;
- our ability to maintain a continued acceptable safety profile of our product candidates following approval, if any, of any of our product candidates;
- significant and changing government regulation and regulatory guidance;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work in light of adverse global market conditions; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products and product candidates. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

General and administrative expenses consist principally of personnel-related costs including payroll and stock-based compensation expense for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, and accounting services, rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase substantially during the next few years as a result of staff expansion and additional occupancy costs, as well as costs associated with being a public company, including compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, higher legal and auditing fees, investor relations costs, higher insurance premiums and other compliance costs associated with being a public company. We also expect that our future intellectual property expenses may increase as we expand our product portfolio of product candidates due to advances in our research and development programs.

Impairment of long-lived assets

Impairment of long-lived assets consists of a one-time impairment charge.

Change in fair value of common warrant liability

Change in fair value of common warrant liability consists of revaluation of the common warrants issued in connection with the June and October 2025 underwritten public offerings (see Note 5). The common warrants are re-measured at each balance sheet date.

Gain on sale of property and equipment

Gain on sale of property and equipment was $0.0 million and $0.5 million for the three and nine months ended September 30, 2026, respectively. No gain on sale of property and equipment was recorded for the three and nine months ended September 30, 2025. The gain in the current period was attributable to proceeds from the sale of laboratory equipment.

Interest and Other Income, Net

Interest and other income, net consists primarily of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the three and nine months ended September 30, 2026 and 2025

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	$ Change	2026	2025	$ Change
Operating expenses:						
Research and development	$ 8,531	$ 14,401	$ (5,870)	$ 26,793	$ 53,864	$ (27,071)
General and administrative	4,432	4,199	233	11,710	15,724	(4,014)
Impairment of long-lived assets	—	2,205	(2,205)	—	2,205	(2,205)
Total operating expenses	12,963	20,805	(7,842)	38,503	71,793	(33,290)
Loss from operations	(12,963)	(20,805)	7,842	(38,503)	(71,793)	33,290
Change in fair value of common warrant liability	6,513	3,872	2,641	10,051	4,099	5,952
Gain on sale of property and equipment	—	—	—	510	—	510
Interest and other income, net	267	526	(259)	1,016	1,285	(269)
Net loss	$ (6,183)	$ (16,407)	$ 10,224	$ (26,926)	$ (66,409)	$ 39,483

Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	$ Change	2026	2025	$ Change
External costs:						
Clinical research organization expenses						
COVALENT - 101	$ —	$ 241	$ (241)	$ —	$ 2,168	$ (2,168)
COVALENT - 102	—	668	(668)	—	1,140	(1,140)
COVALENT - 103	(132)	1,146	(1,278)	370	2,744	(2,374)
COVALENT - 111	(18)	1,032	(1,050)	(18)	4,367	(4,385)
COVALENT - 112	(22)	601	(623)	(22)	1,414	(1,436)
COVALENT - 211	1,883	—	1,883	4,149	—	4,149
COVALENT - 212	919	—	919	2,266	—	2,266
GLP - 131	579	255	324	2,802	255	2,547
Other clinical related expenses	1,251	1,396	(145)	3,252	4,726	(1,474)
Nonclinical activities related expenses	8	1,191	(1,183)	163	4,741	(4,578)
Expenses related to manufacturing of clinical and research material	399	1,420	(1,021)	1,682	3,689	(2,007)
Other external costs	470	1,429	(959)	1,709	5,900	(4,191)
Internal costs:						
Personnel-related expenses (including stock-based compensation)	2,850	3,822	(972)	9,373	17,342	(7,969)
Facilities and other allocated expenses	344	1,200	(856)	1,067	5,378	(4,311)
Total research and development expenses	$ 8,531	$ 14,401	$ (5,870)	$ 26,793	$ 53,864	$ (27,071)

Research and development expenses decreased by $5.9 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The decrease of $4.0 million in external costs was primarily driven by a decrease of $1.2 million related to nonclinical and exploratory programs, a decrease of $1.0 million of manufacturing costs, a decrease of $1.0 million in other external costs related to consultants, advisors and other professional services to support our clinical studies, and a decrease of $0.9 million related to clinical activities. Personnel-related expenses decreased by $1.0 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $0.9 million due to a decrease in rent and facilities-related costs.

Research and development expenses decreased by $27.1 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The decrease of $14.8 million in external costs was primarily driven by a decrease of $4.6 million related to nonclinical and exploratory programs, a decrease of $4.2 million in other external costs related to consultants, advisors and other professional services to support our clinical studies, a decrease of $4.0 million related to clinical activities and a decrease of $2.0 million of manufacturing costs. Personnel-related expenses decreased by $8.0 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $4.3 million due to a decrease in rent and facilities-related costs.

General and Administrative Expenses

General and administrative expenses increased by $0.2 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily driven by an increase of $0.6 million of corporate-related expenses, offset by a decrease of $0.4 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by less than $0.1 million.

General and administrative expenses decreased by $4.0 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The decrease was primarily driven by a decrease of $3.1 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount and a decrease of $0.7 million of corporate-related expenses. Facilities and other allocated expenses decreased by $0.2 million.

Impairment of long-lived assets

Impairment of long-lived assets was $0.0 million for both the three and nine months ended September 30, 2026 and $2.2 million for both the three and nine months ended September 30, 2025, attributable to a one-time impairment charge.

Change in fair value of common warrant liability

Change in fair value of common warrant liability was $6.5 million for the three months ended September 30, 2026 and $3.9 million for the three months ended September 30, 2025, attributable to revaluation of the common warrants issued in connection with the June and October 2025 underwritten public offerings (see Note 5). The common warrants are re-measured at each balance sheet date.

Change in fair value of common warrant liability was $10.1 million for the nine months ended September 30, 2026 and $4.1 million for the nine months ended September 30, 2025, attributable to revaluation of the common warrants issued in connection with the June and October 2025 underwritten public offerings (see Note 5). The common warrants are re-measured at each balance sheet date.

Gain on sale of property and equipment

Gain on sale of property and equipment was $0.0 million for the three months ended September 30, 2026 and September 30, 2025, respectively.

Gain on sale of property and equipment was $0.5 million for the nine months ended September 30, 2026 and $0.0 million for the nine months ended September 30, 2025. The gain in the current period was attributable to proceeds from the sale of laboratory equipment.

Interest and other income, net

Interest and other income, net was $0.3 million for the three months ended September 30, 2026 and $0.5 million for the three months ended September 30, 2025.

Interest and other income, net was $1.0 million for the nine months ended September 30, 2026 compared to $1.3 million for the nine months ended September 30, 2025. The decrease of $0.3 million was primarily due to lower interest rates earned on cash and cash equivalents balance.

Liquidity and Capital Resources

Liquidity

We have funded our operations primarily through the sale and issuance of shares of our common and convertible preferred stock, pre-funded and common warrants and the issuance of unsecured promissory notes from inception through December 2020, issuance of our common stock through our IPO in April 2021, our public offerings in March 2023, June 2025 and October 2025 and through sales under our 2022 ATM Program.

On October 14, 2022, we filed the 2022 Registration Statement with the SEC relating to the registration of up to an aggregate of $350.0 million in shares of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. The 2022 Registration Statement was declared effective by the SEC on October 24, 2022. In April 2023, pursuant to the 2022 Registration Statement, we sold an aggregate of 5,750,000 shares of common stock at a price of $30.00 per share in an underwritten public offering for gross proceeds of $172.5 million, resulting in net proceeds of $161.8 million after deducting underwriting discounts and commissions, and offering costs. On August 5, 2025, we filed the 2025 Registration Statement with the SEC relating to the registration of up to an aggregate of $300.0 million in shares of our common stock, preferred stock, debt securities, warrants and units or any combination thereof to replace the 2022 Registration Statement. The 2025 Registration Statement was declared effective by the SEC on August 15, 2025.

In June 2025, we completed an underwritten public offering, in which we issued and sold 19,450,000 shares of common stock at an offering price of $2.00 per share and to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 550,000 shares of common stock at an offering price of $1.9999 per share, and accompanying common warrants to purchase up to 23,000,000 shares of common stock at a per share exercise price of $2.50. Our net proceeds from the offering were approximately $37.2 million, after deducting underwriting discounts and commissions and offering costs of approximately $2.8 million. In July 2025, in connection with the June 2025 underwritten public offering, the underwriters partially exercised their over-allotment option to purchase an additional 1,381,262 shares of common stock at an offering price of $2.00 per share. The net proceeds from the offering pursuant to the over-allotment option were approximately $2.6 million, after deducting underwriting discounts and commissions and offering costs of approximately $0.2 million.

Additionally, we are party to an equity distribution agreement, dated November 25, 2022, with Piper Sandler with respect to the 2022 ATM Program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $100.0 million (which was included in the $350.0 million originally registered under the 2022 Registration Statement and is now included in the $300.0 million originally registered under the 2025 Registration Statement) through Piper Sandler as the sales agent. Through September 30, 2026, we have received aggregate proceeds from our 2022 ATM Program of $4.9 million, net of commissions and offering costs, pursuant to the issuance of 2,271,122 shares. As of September 30, 2026, we have $94.8 million available under the 2022 ATM Program.

In October 2025, we completed an underwritten public offering in which we issued and sold 11,195,121 shares of common stock at an offering price of $2.05 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 1,000,000

shares of common stock at an offering price of $2.0499 per share and accompanying common warrants to purchase up to 12,195,121 shares of common stock at a per share exercise price of $2.50. Our net proceeds from the offering, including the proceeds from the underwriter's over-allotment option, were approximately $23.1 million, after deducting underwriting discounts and commissions and offering costs of approximately $1.9 million.

As of September 30, 2026, we had cash, cash equivalents, and restricted cash of $26.8 million and an accumulated deficit of $476.0 million. We have incurred substantial operating losses and have used cash in our operating activities since inception. Without any future financing, the current operating plan under the existing cash and cash equivalents, and restricted cash as of September 30, 2026, will only be sufficient to fund our operations into the second quarter of 2027. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations and there can be no assurance that additional financing will be available to us or that such financing, if available, will be available on terms acceptable to us. Accordingly, there is substantial doubt about our ability to continue as a going concern.

Future Funding Requirements

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. 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 scope, timing, progress, duration, costs and results of our clinical trials, drug discovery, nonclinical development activities and laboratory testing for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we discover and develop additional product candidates;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the cost associated with commercializing our product candidates, if they receive regulatory approval;
- our ability to establish and maintain strategic collaborations and other similar partnerships for the development and commercialization of our product candidates; and
- the impact of any global health emergency and adverse global economic conditions on our business, which may exacerbate the magnitude of the factors discussed above.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional 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 or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

See the section of this Quarterly Report on Form 10-Q titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,	
	2026	**2025**
Net cash provided by (used in):		
Operating activities	$ (30,130)	$ (56,429)
Investing activities	550	—
Financing activities	171	44,792
Net decrease in cash, cash equivalents, and restricted cash	$ (29,409)	$ (11,637)

Net Cash Used in Operating Activities

Net cash used in operating activities was $30.1 million during the nine months ended September 30, 2026 and consisted of a net loss of $26.9 million offset by a decrease in net assets of $2.5 million and an increase of non-cash adjustments of $5.7 million. The decrease in net assets consisted primarily of a decrease in prepaid expenses and other current assets of $1.3 million, and a decrease in operating lease liabilities of $1.1 million, offset by an increase in other assets of $0.4 million, an increase in accrued expenses and other current liabilities of $2.6 million and an increase in accounts payable of less than $0.1 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $4.8 million, gain on sale of property and equipment of $0.5 million and a non-cash gain on the change in fair value of warrant liability of $10.1 million.

Net cash used in operating activities was $56.4 million during the nine months ended September 30, 2025 and consisted of a net loss of $66.4 million offset by a decrease in net assets of $1.2 million and non-cash adjustments of $8.8 million. The decrease in net assets consisted primarily of a decrease in prepaid expenses and other current assets of $7.3 million, a decrease in other assets of $0.6 million, a decrease in accounts payable of $6.5 million and a decrease in operating lease liabilities of $1.9 million, offset by an increase in accrued expenses and other current liabilities of $1.7 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $7.7 million, operating lease expense of $1.7 million, depreciation expense of $1.4 million, impairment of property and equipment of $2.2 million and a non-cash gain on the change in fair value of warrant liability of $4.1 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $0.6 million during the nine months ended September 30, 2026.

Net cash provided by investing activities was $0.0 million during the nine months ended September 30, 2025.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.2 million during the nine months ended September 30, 2026 and primarily relates to proceeds from stock option exercises and purchases under the employee stock purchase plan.

Net cash provided by financing activities was $44.8 million during the nine months ended September 30, 2025 and primarily relates to net proceeds of $44.7 million from issuances of common stock and pre-funded warrants under the public offering and the 2022 ATM Program, and $0.1 million of proceeds from stock option exercises and purchases under the employee stock purchase plan.

Contractual Obligations

As of September 30, 2026, there have been no material changes from the contractual obligations and commitments as of December 31, 2025 previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 24, 2026.

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with GAAP. The preparation of these unaudited 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 at the date of the unaudited condensed financial statements, as well as 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our critical accounting policies are described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates" in our Annual Report on Form 10-K filed with the SEC on March 24, 2026 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2026, except as described in Note 2 to the unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K filed with the SEC on March 24, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. There was no material foreign currency risk for the quarter ended September 30, 2026. We held $26.8 million in cash, cash equivalents, and restricted cash as of September 30, 2026. Cash equivalents consisted of money market funds. Restricted cash consisted of two stand-by letters of credit issued to our landlord in connection with the lab leases. We held no interest-bearing liabilities as of September 30, 2026. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Interim Chief Executive Officer and our President and Chief Operating Officer, our principal executive officer and principal financial officer, respectively, conducted 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) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer have concluded that as of such date our disclosure controls and procedures were effective at a reasonable assurance level (i) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

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

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Our business is subject to various risks and uncertainties, including those described below, that we believe apply to our business and the industry in which we operate. You should carefully consider these risks, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to Our Limited Operating History, Business, Financial Condition, Results of Operations, and Need for Additional Capital

We have a limited operating history, limited experience in conducting clinical trials, have not completed the clinical development of any product candidates, have no products approved for commercial sale, and have not generated any revenue, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biotechnology company with a limited operating history with which investors can evaluate our business and prospects. We commenced operations in August 2017, have not completed the clinical development of any product candidates, have no products approved for commercial sale and have never generated any revenue, and our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking nonclinical studies, preparing for and initiating our initial clinical trials, and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. Our lead product candidate, icovamenib, is currently under investigation in Phase II clinical trials in type 2 diabetes and recently concluded a Phase II clinical trial in type 1 diabetes. In September 2025, we announced that we received IND clearance from the FDA for BMF-650, and initiated our ongoing Phase I clinical trial in obese, otherwise healthy volunteers. In October 2026, we announced interim, topline results from our ongoing Phase Ib clinical trial for BMF-650. Further longer-duration studies and additional clinical data will be needed to fully characterize the optimal patient dosing regimen for BMF-650.

We have limited experience as a company in conducting clinical trials and have not successfully completed the clinical development of any product candidates to date. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a company with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We expect our financial condition and results of operations to continue 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.

We have incurred significant net losses in each period since our inception, and we expect to incur significant net losses for the foreseeable future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We are early in our development efforts and have not yet completed the development of any of our product candidates. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products. We have financed our operations primarily through sales of our common stock, warrants and convertible preferred stock.

We have incurred significant net losses in each reporting period since we commenced operations in August 2017. Our net losses were $26.9 million and $66.4 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $476.0 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit additional INDs;
- continue the clinical development of icovamenib for the treatment of patients with type 2 and type 1 diabetes;
- explore the potential clinical utility of icovamenib in other metabolic disorders, including pre-diabetes and obesity;
- conduct clinical development of BMF-650;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues, or other regulatory challenges;
- establish a sales, marketing, and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce, and protect our intellectual property portfolio;
- hire additional clinical, regulatory, and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have not generated any revenue from our product candidates and may never generate revenue or be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery and development of our product candidates.

Our ability to become profitable depends upon our ability to generate revenue. We have not received marketing approval for any product candidate, and we have not generated any revenue from any product sales or other sources since our inception. We do not expect to generate revenue unless or until we successfully complete nonclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. Icovamenib, our lead product candidate, is advancing in clinical development. As such, we face significant translational risk as our product candidates advance further in clinical development, and promising results in nonclinical studies or early clinical trials may not be replicated in later-stage clinical trials. If approved, icovamenib is not intended as a chronic therapy for insulin deficient diabetes, which could further limit our ability to achieve profitability. All of our current and future product candidates will require nonclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely initiation and completion of our nonclinical studies and clinical trials for icovamenib, BMF-650 and our future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- establishing and maintaining relationships with CROs and clinical sites for the ongoing clinical and nonclinical development of icovamenib, BMF-650 and any future product candidates;
- our ability to complete IND-enabling studies and successfully submit and receive authorization to proceed under INDs or comparable regulatory applications;
- whether we are required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy, consistent manufacturing quality, and acceptable risk-benefit profile of our novel small molecule product candidates or any future product candidates;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary regulatory approvals from the FDA and comparable foreign regulatory authorities;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative therapies in our target indications, including diabetes and obesity, and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our current product candidates and any future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without adequate funding.

Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain indications. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on the development of novel small molecules to treat patients with diabetes and obesity. Although we had previously pursued the development of icovamenib in cancer and metabolic diseases, in January 2025, we announced that our strategic focus for icovamenib will be in metabolic disorders and that we would conclude our studies exploring BMF 500's potential in oncology and explore partnerships to advance our oncology assets.

Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. In addition, if our determination to focus our internal resources on the development of icovamenib in metabolic disorders and seek partnerships to advance our oncology assets does not lead to clinical or commercial success, or we otherwise make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the diabetes or obesity disease treatment landscape or in the pharmaceutical, biopharmaceutical or biotechnology industry more generally, our business, financial condition and results of operations could be materially adversely affected.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development

programs or future commercialization efforts.

Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate and conduct clinical trials of, and seek marketing approval for our product candidates. Developing biopharmaceutical products, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed significant amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our current product candidates and advance our future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing, and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our ongoing and planned clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to incur additional costs associated with our continuing operation as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2026 we had $26.8 million in cash, cash equivalents, and restricted cash. Based on our current operating plan, we believe that our existing cash and cash equivalents, and restricted cash as of September 30, 2026, without any future financing, will not be sufficient for us to continue as a going concern for at least one year from the issuance date of the unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. Our estimate as to how long we expect our existing capital resources to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. 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 through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or restrict our operating activities. To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional 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 or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. 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 raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. 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.

Our future capital requirements depend on many factors, including but not limited to:

- the scope, timing, progress, duration, costs and results of our clinical trials, drug discovery, nonclinical development activities, and laboratory testing for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we discover and develop additional product candidates;
- the cost, timing, and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the timing, receipt, and amount of sales from our potential products;
- our need and ability to hire additional management, scientific, and medical personnel;

- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the cost associated with commercializing our product candidates, if they receive regulatory approval;
- our ability to establish and maintain strategic collaborations and other similar partnerships for the development and commercialization of our product candidates; and
- the impact of adverse global economic conditions on our business, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic and political conditions, inflationary pressures, increases in interest rates and disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors.

There is substantial doubt about our ability to continue as a going concern.

To date, we have not generated any revenues from product sales and have incurred significant operating losses in each year since our inception and we anticipate that losses may continue for the next several years or until such time as we can generate substantial revenues and achieve profitability. In connection with the preparation of this Quarterly Report on Form 10-Q for the period ended September 30, 2026, our management has concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of this Quarterly Report on Form 10-Q. Our ability to continue as a going concern is dependent upon raising capital to maintain current operations and continue research and development efforts. We plan to raise additional capital to fund our operations through public or private equity offerings, debt financings, and/or potential collaborations and license arrangement or other sources. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that we will be able to obtain financing or enter into a collaboration on terms acceptable to us.

Based on our current operating plan, we will not be able to continue as a going concern over the next twelve months unless we raise additional capital by other means. These factors raise substantial doubt about our ability to continue as a going concern.

Volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, pursue the nonclinical and clinical development of our product candidates, respond to business challenges or opportunities, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing research and development capabilities;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could require us to pay significant interest on borrowings or involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. Our inability to obtain adequate financing or financing on terms satisfactory to us could have a negative impact on our financial condition and we could face significant limitations on our ability to pursue our business strategies, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past, such as in the case of the closure and subsequent placement into receivership with the Federal Deposit Insurance Corporation (FDIC) of Silicon Valley Bank (SVB) in March 2023, and may in the future lead to market-wide liquidity problems. In these cases, borrowers under credit agreements, letters of credit and certain other financial instruments with any financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. 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 such a 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.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have or may enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions with which we have or may enter into financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or access other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- Potential or actual breach of financial covenants in any credit agreements or credit arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business.

Risks Related to Product Development

Our discovery and development activities are focused on the development of novel small molecule therapies, initially targeted at menin, to treat patients with diabetes and obesity, and the approach we are taking to discover and develop such product candidates is novel, may never lead to marketable products and may not ultimately represent a significant market.

The discovery and development of small molecule therapies for patients with diabetes and obesity, with a particular focus on menin, is an emerging field. While there is scientific evidence to support the feasibility of developing therapies, the significant complexity and potential safety and toxicity concerns associated with poorly designed covalent binders have historically discouraged drug developers from pursuing this drug class. In particular, a significant risk of toxicity is posed by these small molecule binders if they demonstrate a more promiscuous binding profile than intended, which can potentially cause unacceptable levels of off-target interactions. While we believe the significant expertise, foundational knowledge and capabilities that our management team members have accumulated over their extensive careers and that we have expanded and refined since our inception positions us to overcome such challenges, there can be no assurance that we will be successful. Even if we are able to limit off-target interaction, there can be no assurance that treatment with any of our novel small molecule product candidates will demonstrate the deep inactivation of their targets or offer greater therapeutic windows than conventional non-covalent drugs. It is possible that the targets we select, such as menin, could be effectively and safely treated by more frequent dosing of non-covalent drugs, which could limit the potential advantages or perceived benefits of our covalent and non-covalent product candidates.

Our lead product candidate, icovamenib, and our next-generation product candidate, BMF-650, are in clinical development. Our

current data is primarily limited to clinical data in a relatively small patient population for icovamenib, as well as animal models and nonclinical cell lines for icovamenib and BMF-650. These results may not be replicated in larger clinical trials, or, in the case of nonclinical data, translate into humans. As such, even if we are able to develop novel small molecule therapy candidates that demonstrate positive results in nonclinical studies or early-stage clinical trials, there can be no assurance that such product candidates will subsequently demonstrate significant clinical benefit in vivo or in larger trials or will be well-tolerated.

We are early in our development efforts and are substantially dependent on our product candidates, icovamenib and BMF-650. If we are unable to advance icovamenib, BMF-650 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize icovamenib, BMF-650 or any other product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We are early in our development efforts. We have not yet successfully completed clinical testing of our lead product candidate, icovamenib, in human subjects for various types of type 2 diabetes or type 1 diabetes, or our second product candidate, BMF-650, as a next-generation oral GLP-1 RA. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of icovamenib or BMF-650. The success of our product candidates will depend on several factors, including the following:

- our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements, disruptions of staffing and operations at the FDA or other government agencies and timing due to any continued and prolonged public health emergencies;
- successful completion of nonclinical studies, regulatory submissions and clinical trials;
- receipt of authorization to proceed under INDs for our planned clinical trials or future clinical trials;
- successful initiation, patient enrollment in, and completion of current and future clinical trials, including our ongoing Phase II clinical trial of icovamenib in type 2 diabetes and our Phase II clinical trial of icovamenib in insulin-deficient type 2 diabetes as well as our Phase I clinical trial for BMF-650, including the additional cohort in the Phase I clinical trial announced in June 2026;
- successful partnerships to further advance our oncology assets;
- whether icovamenib, BMF-650 or any other product candidates that we may identify and pursue will demonstrate safety, tolerability and efficacy profiles that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- completion of any required post-marketing approval commitments to applicable regulatory authorities in order to maintain marketing authorization for any of our product candidates that receive regulatory approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies for diabetes and obesity;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for our product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which could materially adversely affect our business. If we do not receive regulatory approvals for our current or future product candidates, we will not be able to continue our operations.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional nonclinical and clinical development, management of clinical, nonclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost-effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with

cGMP, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales, if ever. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our nonclinical studies or clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by FDA before implementation, which could delay our nonclinical studies, clinical trials and product candidate development, and could require additional nonclinical studies and clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted an NDA to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights for each product candidate, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

Nonclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our nonclinical and clinical programs may experience delays or may never be initiated or completed, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.

In order to obtain FDA approval to market a novel small molecule product, we must demonstrate the safety and efficacy of our product candidates in humans to meet the FDA requirements. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming, and subject to uncertainty. Before we can commence clinical trials for a product candidate, we must complete extensive nonclinical studies that support our planned and future INDs in the United States. At present, we are advancing two product candidates, icovamenib and BMF-650. We cannot be certain of the timely completion or outcome of our nonclinical studies and clinical trials and cannot predict if the FDA will allow our existing and proposed clinical programs to proceed or continue to proceed, or if the outcomes of our nonclinical studies and clinical trials will ultimately support further development of our programs. Leadership changes at the FDA in the current administration may compound this uncertainty. Our lead product candidate, icovamenib, is in clinical development for type 2 diabetes and we recently concluded a Phase II clinical trial of icovamenib in type 1 diabetes, and we cannot be sure that we will be able to submit INDs or similar applications with respect to additional indications or other product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting nonclinical testing and clinical trials represents a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting nonclinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of nonclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient nonclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- timely completion of nonclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's GLP requirements and other applicable regulations;
- approval by an independent IRB ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable participants to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in

sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;

- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling participants and delays caused by participants withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's Good Clinical Practices (GCPs), or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by continued and prolonged public health emergencies, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing nonclinical studies and clinical trials. Any inability to successfully initiate or complete nonclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products, if and when approved, have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

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

Delays in the completion of any nonclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our nonclinical studies or clinical trials, such as the previous clinical hold imposed by the FDA on our INDs for icovamenib in type 1 and type 2 diabetes, which was lifted in September 2024, that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business,

financial condition and prospects significantly.

The results of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. Successful nonclinical studies and clinical trials cannot provide assurance of successful commercialization.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek regulatory and marketing approvals for their commercial sale. Success in nonclinical studies does not mean that future clinical trials will be successful. For instance, we do not know whether icovamenib or BMF-650 will perform in clinical trials as they have performed in nonclinical studies, nor can we predict how our future product candidates will perform in future nonclinical studies or clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through nonclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates or prevent regulatory approval. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational product candidates, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular participant, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We face risks related to global health emergencies such as a pandemic, epidemic, or outbreak of an infectious disease, which could materially adversely impact our business, results of operations, and financial condition, including our nonclinical studies and clinical trials.

Any global health emergency such as a pandemic, epidemic, or outbreak of an infectious disease, we have experienced, and may in the future experience disruptions that could severely impact our business, nonclinical studies and clinical trials, including:

- delays or difficulties in clinical site initiation, including difficulties in recruiting CROs for our nonclinical studies and clinical site investigators and clinical site staff for our ongoing and planned clinical trials;
- delays or difficulties in enrolling and retaining participants in our ongoing and planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial participant visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of participant data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our CMOs due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruptions or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during any global health emergency.

If we experience delays or difficulties in the enrollment and/or retention of eligible participants in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue our ongoing and planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible participants to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Participant enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible participants may be limited or may result in slower enrollment than we anticipate.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of participants available to us, as some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, 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 participants who are available for our clinical trials at such clinical trial sites. In addition, there may be limited participant pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that participants have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Participant enrollment for our ongoing and planned clinical trials may be affected by other factors, including:

- our ability to identify clinical trial sites and recruit clinical trial investigators with the appropriate capabilities, competencies and experiences;
- size and nature of the participant population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs or other methods of treatment for the disease under investigation, or availability of competing clinical trials;
- the design of clinical trials and whether the FDA or foreign regulatory agencies agree to the design and implementation of the trial;
- participant eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are pursuing;
- clinicians' willingness to screen their participants for biomarkers to indicate which participants may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of participants in our planned clinical trials due to any continued and prolonged public health emergency;
- ability to obtain and maintain participant consents;
- participant referral practices of physicians;
- the ability to monitor participants adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective participants.

These factors may make it difficult for us to enroll enough participants to complete our clinical trials in a timely and cost-effective manner. Our inability to enroll a sufficient number of eligible participants for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of eligible participants for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Type 2 diabetes is a highly heterogeneous disease, and there are over sixty approved therapies being utilized in treating diabetes at various stages of the disease progression, with early lines of therapies largely genericized. There is also a significant industry pipeline of potentially emerging new treatments all addressing patients either in front line or as a follow-on treatment either in monotherapy or in combination.

We expect to initially seek approval of our product candidates in second or later lines of therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. There is no guarantee, however, that our product candidates that we may identify and pursue, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to seeking any such approvals, we may have to conduct additional clinical trials.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that icovamenib and BMF-650, together with our knowledge and scientific resources, provide

us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors, either alone or with their collaborators, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Any drug candidates that we successfully develop and commercialize will likely compete with existing therapies and new therapies that may become available in the future.

The incidence and prevalence for target patient populations of icovamenib and BMF-650 are based on estimates and third-party sources. If the market opportunities for icovamenib and BMF-650 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy and determining indications on which to focus in non-clinical or clinical trials.

The incidence and prevalence for target patient populations of icovamenib and BMF-650 are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for icovamenib, BMF-650 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages. In addition, we believe we are currently the only company in the United States clinically developing small molecule inhibitor specifically against menin. We define ourselves as targeted drug developers focused on covalent small molecule therapeutics and as such expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in discovery and development of covalent binders that may compete with us against menin or related targets at scale and in an integrated way. Even if they do not advance programs with the same mechanism of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile, and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and participant enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapies that target binding against protein targets of interest to us.

To our knowledge, there are no clinical-stage programs that aim to specifically regenerate insulin-producing beta cells in the islets by targeting menin for diabetes. There are over 60 approved agents and therapies being utilized to address diabetes. Such approved agents and therapies are intended to provide specific benefits to patients; however, we are not aware of any successfully addressing the root cause of diabetes, a depleted pool of functional beta cells. Several programs are targeting beta cell proliferation, including DYRK1A inhibitors. However, in addition to specific safety challenges, studies have shown that this approach may not only proliferate beta cells but also other pancreatic cells, which would not necessarily improve the ratio of alpha to beta cells in the pancreas.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology, and other related markets that pursue targeted therapies for patients with diabetes and obesity. Our competitors will also include companies that are or will be developing other targeted therapies, including small molecule, antibody, or protein degraders for the same indications that we are targeting. For example, the

Wegovy® pill was approved in December 2025 and is indicated with a reduced calorie diet and increased physical activity for adults with obesity, or with overweight who also have weight-related medical problems, to help them lose weight and keep it off. Additionally, in April 2026, Foundayo™ was approved for use in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or overweight adults with at least one weight-related comorbid condition. Both products carry boxed warnings. If icovamenib, BMF-650 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their potency, selectivity, inactivation of the target, therapeutic window, safety, convenience, price, the level of generic competition, our ability to market and commercialize the product candidate and the availability of reimbursement from government and other third-party payors. For additional information regarding our competition, see the section of our Annual Report on Form 10-K filed with the SEC on March 24, 2026 titled "Business—Competition."

Our novel small molecule product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational product candidates that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational product candidates we may need to interrupt, delay or abandon their development or limit development to more narrow 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. Treatment-related side effects could also affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

Icovamenib, BMF-500, BMF-650 or future product candidates may be used in populations for which safety concerns may be reviewed by regulatory agencies. For example, if the administration of icovamenib leads to levels of menin inhibition that far exceed those achieved by well-studied non-covalent menin inhibitors, it is possible that participants' responses could be both unexpected and negative. In addition, we or our future collaborators may study icovamenib in combination with other therapies, which may exacerbate adverse events associated with the therapy.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting participants to the clinical trials, participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a number of potentially significant negative consequences, including, but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;

- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy (REMS), which could include a medication guide outlining the risks of such side effects for distribution to participants;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to participants; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

Interim, "top-line", and preliminary data from our clinical trials that we announce or publish from time to time may change as more participants 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 have announced or published, and may continue to publicly disclose, interim, preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

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

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

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, and others in the medical community.

Various factors will influence whether our product candidates, if approved, are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other available medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;

- pricing and the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if any products we develop achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement of newly-approved products from third-party payors is uncertain. Our product candidates may become subject to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, either of which would adversely affect our business. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 24, 2026 titled "Business—Government Regulation—Coverage and Reimbursement."

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may materially change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional

legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

If product liability lawsuits are brought against us, we may incur substantial liabilities, which may not be sufficiently covered by insurance, and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators restrictions on product development plans, or clinical holds;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance that we believe is appropriate for our stage of development, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage and may need to obtain higher levels prior to marketing any of our product candidates if approved. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our product candidates, ensuring regulatory compliance of our future approved products, the company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenue from them or be able to reach or sustain profitability.

Risks Related to Regulatory Process and Other Legal Compliance Matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate icovamenib and our next-generation product candidate BMF-650, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. In February 2026, then former FDA Commissioner publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence would be the FDA's default standard moving forward for novel products, rather than two such trials; this statement was not a formal agency action, and the scope, implementation and durability of this policy position remain uncertain. In June 2026, the FDA issued revised draft guidance clarifying how sponsors can rely on one scientifically rigorous adequate and well-controlled clinical investigation with confirmatory evidence to satisfy the statutory substantial evidence of effectiveness standard. Further, in July 2026, in response to congressional inquiries, the FDA indicated that informal statements, issued through journals or means other than formal notice and comment rule-making, are not reflective of official FDA policy and should not be interpreted as regulatory guidance. The FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial. Additionally, comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may suspend or prohibit completion of our clinical trials, such as through the clinical hold placed on our INDs for the Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes, which was lifted in September 2024, or they may disagree with the design or implementation of our clinical trials or require us to modify the design of our clinical trials, including additional procedures and contingency measures in response to public health emergencies like a pandemic, or as required by clinical sites, IRBs, the FDA or other regulatory authorities;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks, or that a product candidate has an acceptable benefit-risk ratio for its proposed indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- staffing changes and backlogs at the FDA, or other comparable foreign regulatory authorities may create unexpected delays in the review and approval of any applications we may submit;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures,

specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- our third-party contractors may fail to comply with regulatory requirements or otherwise fail or be unable to adequately perform their obligations to allow for the conduct of our planned or future clinical studies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would materially adversely affect our business, results of operations and prospects.

The FDA or a comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

A condition or disease we are conducting or plan to conduct clinical trials for may not be a rare disease or condition that is eligible for orphan drug designation or we may not be able to obtain orphan drug designation or obtain or maintain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities, from approving competing products.

As part of our business strategy, we may seek orphan drug designation (ODD) for any eligible product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for the use or indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same approved use or indication for seven years, except in circumstances such as a showing of clinical superiority to the product with orphan product exclusivity in instances of supply issues.

Even if we obtain ODD for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs may be approved for the same approved use or indication. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same approved use or indication if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

A Breakthrough Therapy designation or Fast Track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States.

We may seek Breakthrough Therapy designation for some of our product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between

the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as Breakthrough Therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track designations for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Accelerated approval by the FDA, even if granted for our current or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion

and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for any products we develop is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of any products we develop in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be adversely affected.

Changes in funding or disruptions at the FDA, the SEC and other government agencies caused by leadership changes, reduction in staffing, funding shortages or global health concerns could hinder their ability to hire and retain 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.

Federal agencies in the U.S., including the FDA and the SEC, operate pursuant to annual appropriations and other political and budgetary processes, and may from time to time be subject to continuing resolutions, funding lapses, or other fiscal constraints. The FDA is currently funded through December 11, 2026. Without appropriation of sufficient funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. Inadequate funding for the FDA, the SEC, the United States Patent and Trademark Office (USPTO) and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner 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. For example, the Trump administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies. In addition, in the current administration, there is substantial uncertainty as to the extent and manner in which the U.S. government will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, leadership and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years and may continue to fluctuate as a result of these factors. Disruptions at the FDA, the SEC, the USPTO and other agencies, including substantial leadership departures, personnel cuts and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, disruptions at the NIH or changes to the NIH's budget may negatively impact our operations and ongoing clinical trials.

For example, the U.S. government has shut down several times. Most recently, from October 1, 2025 through November 12, 2025, the government experienced a full shutdown and from January 31, 2026 through February 3, 2026, the government experienced a partial shutdown, and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. As of February 2026, most government agencies have been funded through December 11, 2026, however if a future prolonged government shutdown occurs again, it could result in significant delays in the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could have a material adverse effect on our business. In addition, government funding of the SEC and 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.

Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Our product candidates and the activities associated with their development and potential commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Following potential approval of any of our current or future product candidates, the FDA or other comparable regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, tracking and tracing requirements, GLP requirements, and GCP requirements, for any clinical trials that we conduct post-approval. Additionally, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, or for discontinuing or interrupting the supply of certain drugs, including the withdrawal of a drug. Failure to do so could result in the FDA sending a noncompliance letter, or placing the product on a list of discontinued products. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, FDA Form 483s, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i)

changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 24, 2026 titled "Business—Government Regulation — Healthcare Reform."

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. Further, FDA's Office of Prescription Drug Promotion (OPDP) actively scrutinizes promotional communications, including digital and social media; any materials that are false, misleading or promote unapproved uses can lead to enforcement actions and could necessitate corrective communications. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Although physicians may prescribe products for "off-label" uses in the exercise of their independent professional judgment, if we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also imposed consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. In the current administration, the FDA has increased its enforcement scrutiny over prescription drug advertising, particularly direct-to-consumer product promotion and advertising. If the FDA finds any of our promotional communications or advertising to be violative, we may receive an untitled or warning letter, requests for corrective advertising, or fines, amongst other enforcement tools available to the FDA.

Our employees, independent contractors, consultants, principal investigators, CROs, suppliers, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, principal investigators, CROs, suppliers, and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and material adversely affect to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm,

diminished profits and future earnings and the curtailment or restructuring of our operations.

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

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider payment transparency laws and regulations. If their operations are found to be in violation of any such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 24, 2026 titled "Business—Government Regulation—Other Healthcare Laws."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may be compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are or may become subject to stringent and changing laws, regulations, contractual obligations, and other obligations relating to privacy, data protection, and information security. The actual or perceived failure by us or our partners, customers, vendors, third-party payors or other related third parties to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

There are numerous domestic and foreign laws, regulations, and other legal obligations regarding privacy, data protection, and information security, the scope of which are changing and subject to differing applications and interpretations, and which may be inconsistent among jurisdictions or conflict with each other. Privacy, data protection, and information security laws and regulations worldwide are, and are likely to remain, uncertain for the foreseeable future, and the actual or perceived failure to address or comply with them by us or our partners, customers, vendors, or other related third-parties could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers; reduce the use of our products, result in litigation and liability, cause a material adverse impact to business operations or financial results, or otherwise result in material harm to our business.

In the U.S., numerous states have in recent years introduced and enacted more and more comprehensive privacy, data protection, and information security laws, adding complexity, variation in requirements, restrictions and potential legal risk requiring additional investment of resources in compliance programs. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, affords consumers expanded privacy protections, including expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used. Similar privacy laws have been proposed at the federal level and in other states, creating a complicated national patchwork. Furthermore, some states have proposed or enacted legislation specifically focused on health privacy, such as Washington's My Health My Data Act, with similar statutes in Nevada and Connecticut. The effects of state privacy laws are significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Additionally, we are or may become subject to the terms of internal and external policies, representations, standards, contractual obligations, and other obligations to third parties related to privacy, data protection, and information security. Our actual or perceived

failure to comply with them may cause us to suffer a material adverse impact to our business operations or financial results, or otherwise result in material harm to our business.

Moreover, in the United States, most healthcare providers, including research institutions from which we obtain participant health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH, and their respective implementing regulations. Compliance with HIPAA and HITECH may require us to modify our data processing policies and to incur substantial costs and expenses.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Additionally, we may use and integrate artificial intelligence into our business processes, both in our own development and implementation of artificial intelligence through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, information technology, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of artificial intelligence technologies. A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of artificial intelligence, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of artificial intelligence and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict.

We may in the future receive inquiries or be subject to investigations, proceedings, or actions by governmental entities, or litigation by private parties, regarding our privacy, data protection, and information security practices, which could result in a material adverse impact to our business operations or financial results, or otherwise result in material harm to our business, including without limitation, interruptions of or requirements to make changes to our business practices, the diversion of resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary data processing, or other remedies that adversely affect our business.

The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business, including by posing security and other risks to our confidential and/or proprietary information, including personal information, and, as a result, we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence into our business processes, and this innovation presents risks and challenges that could affect its adoption and, therefore, our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development, and compliance in this area. For example, the EU's Artificial Intelligence Act (the EU AI Act)—the world's first comprehensive artificial intelligence law—entered into force in June 2024 and, with some exceptions, becomes effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. Likewise, in the United States, the regulatory environment is complex and uncertain. President Trump's Executive Order "Ensuring a National Policy Framework for Artificial Intelligence," effective December 11, 2025 (the Executive Order), tasks the U.S. Department of Justice with reviewing state laws regulating artificial intelligence, and instructs the Department of Commerce to develop a national artificial intelligence strategy. At the same time, several states, including Colorado and California, passed laws that regulate various facets of artificial intelligence, some of which have taken effect and will continue to take effect through 2026 and beyond. These laws address a wide range of artificial intelligence-related topics, including consequential decisions, transparency, training data, among others, and it remains unclear which requirements, if any, will be superseded by the Executive Order. In addition, there continues to be uncertainty regarding the application of existing federal and state legal frameworks to uses and development of artificial intelligence, and legal norms and market standards regarding artificial intelligence continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of artificial intelligence in regulated sectors. The FDA, for example, issued draft guidance on the use of artificial intelligence in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating artificial intelligence model outputs intended to support regulatory decision-making. In the future, if we develop or use artificial intelligence systems that are governed by the EU AI Act or any other artificial intelligence legislation in effect,

and further informed by regulatory guidance, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, 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 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 product 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.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, 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. Such Trade Laws also govern export controls, as well as economic sanctions and embargoes on certain countries and persons. We 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 to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and 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. Violations of Trade 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.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

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

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Operating Officer and President, Ramses Erdtmann. The departure of key leadership personnel, such as the departures of our former Chief Executive Officer and Chief Financial Officer in 2025, may result in loss of significant knowledge and experience from the company. This loss of knowledge and experience can be mitigated through successful hiring and transition, but there can be no assurance that we will be successful in such efforts. Attracting and retaining qualified senior leadership may be more challenging under adverse business conditions. We will need to hire additional personnel as we initiate and expand our clinical development and if we initiate commercial activities. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be adversely affected.

Additionally, we rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. 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. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be materially adversely affected.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in achieving and managing this growth.

As of September 30, 2026, we had 34 full-time employees, including 21 employees engaged in research and development activities.

In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial clinical, regulatory, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, and other comparable foreign regulatory agencies' review process for icovamenib, BMF-650 and any future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving and maintaining our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize icovamenib, BMF-650 and future product candidates will depend, in part, on our ability to effectively achieve and manage any future growth in company headcount. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our nonclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of icovamenib, BMF-650 or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize icovamenib, BMF-650, or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Business disruptions could materially adversely affect our future revenue and financial condition and increase our costs and expenses.

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

Our ability to develop icovamenib, BMF-650 or any future product candidates we may develop could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions. Our corporate headquarters are

located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and business could suffer in the event of a major earthquake, fire or other natural disaster.

Our ability to utilize our NOLs carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our NOL carryforwards that we generate in the future may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under current U.S. tax law, our federal NOLs generated in taxable years beginning after December 31, 2020 may be carried forward indefinitely, but such deductibility is limited to 80% of current year taxable income.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change (by value) in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income or tax liabilities may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have performed a Section 382 study and concluded that our ability to utilize our NOLs and certain other tax attributes could be limited by an ownership change as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. In recent years, many changes to tax laws have been made, and changes are likely to continue to occur in the future. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. Although the OBBBA has not materially impacted our effective tax rate or cash flows in the current fiscal year, it cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

A portion of our chemistry-based product development and sourcing of certain manufacturing raw materials for our product candidates takes place outside the United States through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We currently contract certain product development and manufacturing operations to third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers to support the development of our product candidates. Any disruption in production or inability of our manufacturers outside the United States to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located outside the United States, 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 other foreign governments, political unrest or unstable economic conditions in these jurisdictions. In particular, the United States in July 2026 imposed baseline tariffs generally ranging from 10% - 12.5% on a substantial portion of U.S. imports. The United States also has imposed higher tariffs on certain pharmaceutical products. As such, a trade war or other trade restrictions could lead to additional tariffs on the chemical intermediates we use that are manufactured in China.

In addition, U.S. legislation, referred to as the BIOSECURE ACT, went into effect on December 18, 2025 as part of the National Defense Authorization Act of 2026, may have the effect of restricting the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies of concern without losing the

ability to contract with, or otherwise receive funding from, the U.S. government. Any of these matters could materially adversely affect our business, financial condition and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to foreign currency fluctuations in the value of the local currency as future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines outside the United States, including in China.

Risks Related to Reliance on Third Parties

We currently rely, and plan to rely in the future, on third parties to conduct and support our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our nonclinical studies and clinical trials under agreements with us. We are continuing to build our internal chemistry, manufacturing and controls, biology and nonclinical development capabilities to supplement activities conducted by third parties on our behalf. As part of this personnel build out, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

We will rely heavily on these third parties over the course of our nonclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these nonclinical studies and clinical trials and the management of data developed through nonclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. The FDA has signaled that foreign GCP inspections will be increasing alongside transparency of GCP inspection outcomes. In addition, our clinical trials must be conducted with pharmaceutical product produced under current Good Manufacturing Practices (cGMP) regulations and will require a large number of test participants. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of participants may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our nonclinical studies or clinical trials will not be our employees and, except for remedies available to

us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting nonclinical studies, clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our nonclinical or clinical protocols or regulatory requirements or for other reasons, our nonclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our nonclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We currently rely and expect to rely in the future on the use of dedicated manufacturing suites in third-party facilities or on third parties general manufacturing facilities to manufacture our product candidates, and we may rely on third parties to develop processes and testing methods for our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to develop appropriate processes and testing methods to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own or lease any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other comparable foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, qualified personnel, their equipment and facilities and any applicable licenses or approvals. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and delays, and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other comparable foreign regulatory authority must inspect any manufacturers for cGMP compliance as part of our marketing application;
- manufacturing processes and testing methods may need to be transferred to a new manufacturer, or we or others on our behalf may need to develop substantially equivalent processes and testing methods for, the production of our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA or other comparable foreign regulatory authority and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these changing and tightening regulations and standards;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- our third-party manufacturers may experience change of control of their ownership including ownership by a competitor,
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available at acceptable prices, or at all, or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance, qualified personnel, their equipment and facilities and any applicable licenses or approvals.

In addition, from time to time we have relied upon, and may continue to rely upon, third-party contract manufacturers that are based in jurisdictions outside the United States. Legislation was proposed that, if enacted, could have negatively impacted U.S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. If any of our third-party manufacturers are impacted by these legislative proposals, the potential downstream adverse impacts on us are unknown but may include supply chain disruptions or delays.

Our business could be materially adversely affected by any business disruptions to our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the initiation or completion of any clinical trials or the approval of any of our product candidates by the FDA or other comparable foreign regulatory authority, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA or other comparable foreign regulatory authority could place significant restrictions on our company until deficiencies are remedied.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and the manufacturing processes required to develop, our product candidates.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, raw materials, components and materials used in, and development activities required to manufacture our product candidates. There are, for certain of these components, relatively few alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs, be able to supply materials or services to us at cost that are acceptable to us, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, ingredients, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates may be interrupted for an extended period, which could materially adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in or for our product candidates, if required, may not be accomplished quickly and would create increased cost, or adversely impact the quality of our product candidates. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, would need to process our technology transfer and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source ingredients, components and materials used in our product candidates, any interruption or delay in the supply of ingredients, components or materials or our inability to obtain ingredients, components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers may use highly flammable reagents at high reaction temperature, are subject to federal, state and local laws and regulations in the United States and their country governing the use,

manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards and regulations, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We have and may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We have and may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product 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 product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into future collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and

results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and/or acquire intangible assets that could result in significant future amortization expense.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, enforce and adequately protect our patents and other intellectual property rights with respect to our technology and product candidates, or if the scope of our patents or other intellectual property rights are not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology or product candidates may be adversely affected.

We rely on a combination of patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technology and product candidates, and our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to such technology and product candidates. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secret protections cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual and scientific questions and can be uncertain. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products.

The patent applications that we own may fail to result in issued patents with claims that cover our technology or product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our technology or product candidates, third parties may challenge the inventorship, ownership, validity, enforceability or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not issue to protect our technology or product candidates or which effectively prevent others from developing, manufacturing or commercializing competitive technologies and product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. This will require us to be cognizant of the time from invention to filing of a patent application, and beyond.

If the breadth or strength of protection provided or potentially provided by the patents and patent applications we hold with respect to our technology or product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Furthermore, even if our patents and patent applications are unchallenged, they

may not adequately protect our intellectual property, provide exclusivity for our technology and product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create similar or alternative technologies, products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may become involved in litigation, opposition, interference, derivation, post grant review, *inter partes* review or other proceedings challenging our patent rights, and the outcome of any proceedings are highly uncertain. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Filing, prosecuting 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 countries do not protect intellectual property rights to the same extent as 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 countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

However, trade secrets can be difficult to protect and trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and even then, the license may not be available on commercially reasonable terms. Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, consultants, scientific advisors and other contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets could be disclosed, and we may not have adequate remedies for any such breach.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

Our success depends in part on our ability to protect our intellectual property rights. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to protect our intellectual property rights throughout the world.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and product candidates and any future products. These candidates include icovamenib and others, their respective components, formulations, methods used to manufacture them and methods of treatment. Our commercial success will also depend on successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our technology, product and product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent prosecution process is expensive and time-consuming, and we 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 may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights or we may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed.

If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology or product, we may require a license from the competitor, and if then the license may not be available on commercially reasonable terms.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any issued patents we may own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, there might be 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 a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale

of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially-reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

We may become involved in lawsuits or litigation at the USPTO to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe or otherwise violate our or our future licensor's patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file infringement, misappropriation or other intellectual property-related claims against such parties, which can be expensive and time consuming. To counter infringement or other unauthorized use, we may be required to file claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question.

In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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 such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Even if we establish infringement, misappropriation or other violation of our intellectual property, the court may decide not to grant an injunction against further such activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. The USPTO hears post-grant proceedings, including post grant review (PGR), *inter partes* review (IPR), and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our technology, products and product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our

intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our or future licensor's patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. United States Congress has in recent years considered legislation to reduce the term of certain drug patents in order to ease generic entry and increase competition. Evolving judicial interpretation of patent law could also adversely affect our business. For example, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our technology or product candidates. Also, former employees may become employed by competitors who develop similar technology or product candidates, and could assist the competitor in designing around our patents or trade secrets. While it is our policy to require our employees and contractors who may be involved in the development of our 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our technology or product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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 use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and any products that we develop. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such lawsuits will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our technology, product candidates and products and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our technology, product candidates and products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our technology, product candidates or products infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our technology, product candidates and products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and

publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our technology, product candidates and/or products infringe or misappropriate their intellectual property rights.

If a third party claims that we infringe or misappropriate its intellectual property rights, we may face a number of issues, including, but not limited to: infringement, misappropriation and other intellectual property related claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business; substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement or misappropriation was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; a court prohibiting us from developing, manufacturing, marketing or selling our products or product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us; however, the third party is not required to grant the license; if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and redesigning our technology, product candidates or products so they do not infringe such third party patents; redesign may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO, or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our technology, product candidates or products.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements 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. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development 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 substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our

ability to compete in the marketplace.

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

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights from third parties in the future. For example, our programs may involve additional product candidates that may require the use of proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. Thus, we may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. These intellectual property license agreements may impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses in the future from third parties to advance our research or allow commercialization of our technology, product candidates or products, and we cannot provide any assurances that there are no third-party patents which might be enforced against our technology, product candidates or products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected technology, product candidates or products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property from third parties may become of critical importance to our business, which involves complex legal, business and scientific issues. Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- 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 on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially reasonable terms, we may not be able to successfully develop and commercialize the affected technology, product candidates or products, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, 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 our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents or intellectual property rights of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Our Common Stock

The price of our stock has been and is likely to continue to be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock has been and is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere herein, these factors include:

- the timing, progress, costs and results of our ongoing, planned or any future clinical trials, clinical development programs or nonclinical studies;
- the commencement, enrollment, progress or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in nonclinical studies and clinical trials such as the clinical hold on our INDs for the Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes, from June 2024 to September 2024;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial, including due to the suspension of a clinical trial by the FDA or other regulatory authorities;

- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our product candidates and any future products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate supply for any of our product candidates or the components thereof, or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- our ability to develop our product candidates for the treatment of type 1 and type 2 diabetes or other metabolic diseases;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or menin inhibitors in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock or securities exercisable for or convertible into shares of our common stock, by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- the impact of any natural disasters or public health emergencies;
- inflationary pressures and general economic, political, industry and market conditions; and
- other events or factors, many of which are beyond our control.

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 addition, the stock market in general, and the market for 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 particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been volatile. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed the price at which you purchased shares of our common stock, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would materially adversely affect our business, financial condition and results of operation.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation preferences or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships, alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. A significant portion of our outstanding shares of common stock are held by a small number of stockholders, including our directors, officers and significant stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

We have also registered or intend to register all shares of our common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. As a result, these shares will be available for sale in the public market subject to vesting arrangements and exercise of options, and restrictions under applicable securities laws. In addition, our directors, executive officers and certain affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or upon the exercise of outstanding warrants, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In November 2022, we entered into our 2022 ATM Program, which provides for the offering, issuance and sale by us of shares of our common stock from time to time for aggregate gross proceeds of up to $100 million in sales deemed to be "at-the-market offerings" as defined by the Securities Act. During the three months ended September 30, 2026, we did not sell any shares pursuant to our 2022 ATM Program.

In April 2023, we sold 5,750,000 shares of common stock at $30.00 per share for gross proceeds of $172.5 million under the registration statement on Form S-3. In June 2025, we issued and sold 19,450,000 shares of common stock at an offering price of $2.00 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 550,000 shares of common stock at an offering price of $1.9999 per share and accompanying common warrants to purchase up to 23,000,000 shares of common stock at a per share exercise price of $2.50. In August 2025, we filed a registration statement on Form S-3 relating to the registration of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. In October 2025, pursuant to a registration statement on Form S-3 filed in August 2025, we issued and sold 11,195,121 shares of common stock at an offering price of $2.05 per share and, to a certain investor in lieu of common stock, pre-funded warrants to purchase up to 1,000,000 shares of common stock at an offering price of $2.0499 per share and accompanying common warrants to purchase up to 14,024,389 shares of common stock at a per share exercise price of $2.50, which included the underwriters' partial exercise to purchase additional common warrants. Any exercises of the common stock warrants issued in the June 2025 or October 2025 underwritten public offerings and any additional sales or issuances of securities pursuant to our 2022 ATM program, our August 2025 registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline. Furthermore, new investors purchasing securities that we may issue and sell in the future could obtain rights superior to the rights of our existing stockholders.

We are also authorized to grant stock options and other equity-based awards to our employees, directors and consultants pursuant to our 2021 Plan and our 2023 Inducement Equity Plan (the Inducement Plan). The number of shares available for future grant under the 2021 Plan will automatically increase each year on January 1, from January 1, 2022 to January 1, 2031, by the lesser of (A) five percent of the shares of Common Stock outstanding on the last day of the immediately preceding fiscal year and (B) such smaller number of shares as determined by the Board or the Committee (as defined in the 2021 Plan). We have also reserved shares of common stock for issuance pursuant to our ESPP which number of shares will automatically increase each year on January 1, from January 1, 2022 to January 1, 2031, by the lesser of (i) one percent of the shares of Common Stock outstanding on the last day of the immediately preceding fiscal year and (ii) such number of shares as may be determined by the Board (as defined in the ESPP); provided, however, no more than 4,500,000 shares may be issued under the ESPP. Currently, we plan to register any increase in the number of shares available for issuance under the 2021 Plan, the ESPP and the Inducement Plan promptly following the effectiveness of any such increase. If our Board elects to increase the number of shares available for future grant under the 2021 Plan, the ESPP or the Inducement Plan, our stockholders may experience additional dilution, and our stock price may fall.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities, which would adversely affect the liquidity of our common stock and could decrease the market price of our common stock.

Our common stock is currently listed on Nasdaq, which has minimum requirements that a company must meet in order to remain listed on that market, including, maintaining a minimum closing bid price of $1.00 per share and certain corporate governance requirements such as Nasdaq Listing Rule 5605(c)(2)(A) (Rule 5605(c)(2)(A)), which requires companies listed on Nasdaq to have an audit committee consisting of three independent directors. In March 2025, we notified the Listing Qualifications Department of Nasdaq that we were not in compliance with Rule 5605(c)(2)(A) due to having only two members on the audit committee of our Board. In July 2025, we appointed Julianne Averill to serve as a member of the Board and our audit committee and regained compliance with Rule 5605(c)(2)(A). However, there can be no assurance that we will be able to continue to satisfy Nasdaq's continued listing requirements with respect to audit committee composition, the minimum bid price requirement or otherwise. If we fail to maintain compliance with Nasdaq's continued listing requirements and a final determination is made by Nasdaq that our common stock must be delisted, our common stock could cease to be listed for trading on Nasdaq and instead be available for trading only over-the-counter, our ability to raise additional funds and the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease. Our failure to be listed on Nasdaq or another national securities exchange would have a material adverse effect on the value of your investment in us.

Our management and directors own our stock and may be able to exert influence over matters subject to stockholder approval.

Our executive officers, directors and their respective affiliates beneficially own approximately 7% of our outstanding voting stock as of September 30, 2026. These stockholders, acting together, may be able to impact matters requiring stockholder approval, particularly if their collective ownership in our company increases. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or

paid on our capital stock. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our Board that our stockholders might consider favorable. These provisions, among other things:

- establish a classified Board so that not all members of our Board are elected at one time;
- permit only the Board to establish the number of directors and fill vacancies on the Board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our Board could use to implement a stockholder rights plan (poison pill);
- 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;
- authorize our Board to amend the bylaws;
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this report. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. 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, other employees or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our

compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our Board or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may materially adversely affect our cash position.

General Risk Factors

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

The market price of our common stock may be volatile and, 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. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially adversely affect our business.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll participants in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for our current and future product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our product candidates and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for our future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain future collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC has adopted significant corporate governance and executive compensation related rules and regulations, such as “say on pay” and proxy access. While emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of the IPO, we cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of any products that we develop, if approved. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers.

As a result of being a public company, we are obligated to develop and maintain proper and effective controls over financial reporting. If we fail to maintain proper and effective internal controls over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal controls over financial reporting. However, while we remain an "emerging growth company," as defined in the JOBS Act, or a smaller reporting company with less than $100 million in revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. 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 the requirements of being a reporting company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal controls over financial reporting is effective, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

We previously identified a significant deficiency in our internal controls over financial reporting pertaining to our fiscal year ended December 31, 2024 and although it has been remediated, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain internal controls 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 controls 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 controls over financial reporting once that firm begins its Section 404 reviews, we could lose investor 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 the Nasdaq Global Select Market, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal controls 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.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act the regulations of the Nasdaq Global Select Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal controls over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. We are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act, and we may experience difficulty in meeting these reporting requirements in a timely manner.

We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements which may result in substantial costs. Any disruptions or difficulties in implementing or using our finance and accounting systems could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal controls over financial reporting will not prevent or detect all errors and all fraud. A control

system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities.

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 24, 2026 titled "Financial Statements and Supplementary Data—Notes to Financial Statements—Recent Accounting Pronouncements."

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company and, for as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements; and
- exemptions from the requirements of holding non-binding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2026.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would

allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the OBBBA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the OBBBA may affect us, and certain aspects of the OBBBA could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the OBBBA or any other newly enacted federal tax legislation. Changes in the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the OBBBA or future reform legislation 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability and changes in fiscal policy, including higher interest rates. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

For example, on October 1, 2025, the U.S. federal government shutdown through November 12, 2025, suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. If we experience another government shutdown, it could result in increased uncertainty and volatility in the global economy and financial markets which could have a material adverse effect on our business. Weak economic conditions or significant uncertainty regarding the stability of financial markets related to stock market volatility, inflation, recession, changes in tariffs or other trade restrictions, trade agreements, trade wars or governmental fiscal, monetary and tax policies, among others, could adversely impact our business, financial condition and operating results.

If our security measures are compromised, or the security, confidentiality, integrity, or availability of our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse impact.

If we or third parties related to us (such as our partners, CROs, and CMOs) experience any material cybersecurity incidents that result in any deletion or destruction of, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of, sensitive, confidential, or proprietary information, including trade secrets, other intellectual property, and personal information (Sensitive Information), or a compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications, or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, indemnity obligations, delays to the development and commercialization of our product candidates, disruption of our programs, negative publicity, and financial loss. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Systems containing Sensitive Information are vulnerable to service interruptions, malfunction, natural disasters, terrorism, war, software and hardware failures, telecommunication and electrical failures, theft or loss from inadvertent or intentional actions by employees, contractors, consultants, business partners and/or other third parties, malware, malicious code (such as viruses and worms), software bugs, ransomware, denial-of-service attacks (including credential stuffing), social engineering and other means that affect service reliability and threaten the security, confidentiality, integrity and availability of information.

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are

working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and now include potential attacks enhanced or facilitated by artificial intelligence. We or third parties related to us may also experience cybersecurity incidents, data breaches or other compromises that may remain undetected for an extended period. Further, we have outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our Sensitive Information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may also be vulnerable to disruptions in service and unauthorized access or misuse of our Sensitive Information. Like other companies in our industry, we, and third parties related to us, have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure.

While we implement commercially reasonable information security safeguards, consistent with companies of the same size and scope as ours, there is no guarantee that our security efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties related to us, will prevent breakdowns, data breaches or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, misuse, or dissemination of, or damage to, Sensitive Information that could have a material adverse impact. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems, data breaches, cybersecurity incidents, or other compromises could result in the loss, misappropriation and/or unauthorized access, use or disclosure or other compromise of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal information and Sensitive Information), which could result in a material adverse impact including financial, legal, business and reputational harm. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial participants or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under privacy, data protection, and information security laws and regulations, including litigation and governmental investigations and fines or penalties, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact.

Notifications and follow-up actions related to a cybersecurity incident or data breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent cybersecurity incidents and data breaches, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach, incident, or compromise. We also rely on third parties to manufacture our product candidates, and similar material events relating to their computer systems could also have a material adverse impact. To the extent that any disruption or data breach, cybersecurity incident, or compromise were to result in a loss, destruction, misuse, or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with applicable privacy, data protection, and information security laws and regulations. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations.

Moreover, our use of new and evolving technologies, such as artificial intelligence, in our operations and the operations of third parties upon which we rely, presents new risks and challenges that could negatively impact our business, including cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges. For example, our use of artificial intelligence-based software may lead to inadvertent release, disclosure, or compromise of Sensitive Information or other confidential information through the use of generative artificial intelligence tools, or other cybersecurity incidents may arise that may impact us.

Our insurance policies, including cybersecurity liability insurance, may not be adequate to compensate us for the potential losses arising from any such cybersecurity incident, data breach, or compromise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations may 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 or injury from these materials. In the event of contamination 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. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these 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 our stock price or trading volume to decline.

Our business could be negatively impacted by corporate citizenship and environmental, social and corporate governance (ESG) matters and/or our reporting of such matters.

There is an increasing focus from certain investors, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Geopolitical events and conditions could adversely affect our business, financial condition and operating results.

Changes in U.S. government and other nations' administrations and their associated shifts in policy and priorities could also impact our operations and market conditions. Our business is sensitive to geopolitical issues, including foreign policy actions taken by governments such as tariffs, sanctions, embargoes, export and import controls, and other trade restrictions, which can affect the demand for, and our ability to sell, our products and services, cause disruptions to our supply chain, and, ultimately, could adversely affect our business. Global conflicts, including Russia's invasion of Ukraine, conflicts in the Middle East, and heightened tensions in the Pacific region, have significantly elevated global geopolitical tensions and security concerns. Economic sanctions, export controls, and other trade restrictions could directly and indirectly result in the disruption of our business and supply chain. Although we do not have any clinical trial sites or operations in the currently affected regions, if the current conflict expands further into the region or continues, resulting heightened economic sanctions from the United States and the international community, in addition to environmental regulations, could limit our ability to procure or use certain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. We continue to monitor any adverse impact that the outbreak of war and the subsequent institution of sanctions by the United States and other countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and third parties with whom we conduct business.

Significant political, trade, or regulatory developments in the jurisdictions in which we sell our products, if approved, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. In particular, the United States in July 2026 imposed baseline tariffs generally ranging from 10% - 12.5% on a substantial portion of U.S. imports. The United States also has imposed higher tariffs on certain pharmaceutical products. These and other U.S. tariff actions have led governments of other countries to undertake retaliatory trade actions, and may result in further retaliatory tariffs. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented or threatened to implement retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

ESG matters may impact our business and reputation.

In addition to the changing rules and regulations related to ESG matters imposed by governmental and self-regulatory organizations, a variety of third-party organizations, institutional investors and customers evaluate the performance of companies on ESG topics, and the results of these assessments are widely publicized. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. Reduced access to or increased cost of capital may occur as financial institutions and investors increase expectations related to ESG matters.

Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG-related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, social investments and other ESG-related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Furthermore, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals, including our previously announced commitments to reduce greenhouse gas emissions, within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. In addition, in recent years “anti-ESG” sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted “anti-ESG” policies, legislation, or initiatives or issued related legal opinions, and the President having recently issued an executive order opposing diversity equity and inclusion (DEI) initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in us facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

(c) *Insider Trading Arrangements*

During the quarter ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a plan or other arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangements under the Exchange Act.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as currently in effect	8-K	4/20/2021	3.2	
3.2	Amended and Restated Bylaws, as currently in effect	8-K	4/20/2021	3.4	
4.1	Form of Common Stock Certificate	S-1/A	4/12/2021	4.2	
4.2	Description of Registrant's Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	3/24/2026	4.2	
4.3	Investors' Rights Agreement, dated December 18, 2020, by and among the Registrant and the investors listed therein	S-1	3/26/2021	10.1	
4.4	Form of Pre-Funded Warrant	8-K	10/7/2025	4.1	
4.5	Form of Common Stock Warrant	8-K	10/7/2025	4.2	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
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.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

BIOMEA FUSION, INC.

Date: November 10, 2026

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)

Date: November 10, 2026

By: /s/ Rainer Erdtmann

Rainer Erdtmann
Chief Operating Officer, Director
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Michael J.M. Hitchcock, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biomea Fusion, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 10, 2026

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Rainer Erdtmann, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biomea Fusion, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 10, 2026

By: /s/ Rainer Erdtmann

Rainer Erdtmann
Chief Operating Officer, Director
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Biomea Fusion, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2026

By: /s/ Michael J.M. Hitchcock
Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Biomea Fusion, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2026

By: /s/ Rainer Erdtmann

Rainer Erdtmann
Chief Operating Officer, Director
(Principal Financial and Accounting Officer)