UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2026

OR

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

Commission File Number: 001-39980

Faeth Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1863385**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
701 Tillery Street #12 #1010 Austin, TX	**78702**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (512) 200-2982

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 per share	FTH	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 July 30, 2026, the registrant had 25,840,425 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

FAETH THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 26,903	$ 8,668
Marketable securities	159,538	12,516
Prepaid expenses	1,359	231
Other current assets	858	92
Total current assets	188,658	21,507
Right-of-use assets - operating leases, net	524	1,294
Right-of-use assets - financing leases, net	—	1
Property and equipment, net	44	82
Other non-current assets	80	18
Total assets	$ 189,306	$ 22,902
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,573	$ 1,481
Compensation and employee benefits liabilities	1,415	1,320
Operating lease liabilities, current	592	1,370
Financing lease liabilities, current	—	80
Total current liabilities	9,580	4,251
Operating lease liabilities, non-current	—	59
Other non-current liabilities	1	—
Total liabilities	9,581	4,310
Commitments and contingencies (Note 7)		
Series B redeemable convertible preferred stock, $0.0001 par value; 502 and zero shares authorized as of June 30, 2026 and December 31, 2025, respectively; 502 and zero shares issued and outstanding as of June 30, 2026, and December 31, 2025, respectively; liquidation value of $0 as of June 30, 2026	6,767	—
Stockholders' equity:		
Preferred stock, $0.0001 par value and 10,000,000 shares authorized as of June 30, 2026 and December 31, 2025; zero shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of June 30, 2026 and 12,500,000 shares authorized as of December 31, 2025; 25,832,969 and 1,261,685 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	2	—
Additional paid-in capital	642,399	301,728
Accumulated deficit	(469,380)	(283,137)
Accumulated other comprehensive (loss) income	(63)	1
Total stockholders' equity	172,958	18,592
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	$ 189,306	$ 22,902

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

FAETH THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 9,180	$ 2,533	$ 27,137	$ 6,258
General and administrative	9,205	2,673	28,918	6,222
Acquired in-process research and development	—	—	132,957	—
Total operating expenses	18,385	5,206	189,012	12,480
Loss from operations	(18,385)	(5,206)	(189,012)	(12,480)
Other income (expense), net:				
Interest income, net	2,258	311	2,650	703
Other income (expense), net	120	(41)	119	(23)
Net loss	$ (16,007)	$ (4,936)	$ (186,243)	$ (11,800)
Net loss per common share, basic and diluted	$ (2.84)	$ (3.91)	$ (53.50)	$ (9.36)
Weighted-average shares outstanding, basic and diluted	5,643,222	1,260,867	3,481,149	1,260,202
Comprehensive loss:				
Net loss	$ (16,007)	$ (4,936)	$ (186,243)	$ (11,800)
Other comprehensive items:				
Unrealized (loss) gain on marketable securities	(39)	(5)	(64)	2
Total other comprehensive (loss) income	(39)	(5)	(64)	2
Total comprehensive loss	$ (16,046)	$ (4,941)	$ (186,307)	$ (11,798)

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

FAETH THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, COMMON STOCK AND STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share data)

For the six months ended June 30, 2026 and 2025

	Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2024	—	$ —	1,258,940	$ —	$ 300,451	$ (262,052)	$ (13)	$ 38,386
Stock-based compensation expense	—	—	—	—	461	—	—	461
Surrender of shares for tax withholding	—	—	(390)	—	(3)	—	—	(3)
Vesting of restricted stock shares	—	—	1,768	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	—	7	7
Net loss	—	—	—	—	—	(6,864)	—	(6,864)
Balance at March 31, 2025	—	—	1,260,318	—	300,909	(268,916)	(6)	31,987
Stock-based compensation expense	—	—	—	—	264	—	—	264
Employee stock purchase plan expense	—	—	1,004	—	5	—	—	5
Cash-in-lieu of fractional shares for reverse stock split	—	—	(32)	—	(1)	—	—	(1)
Unrealized loss on marketable securities	—	—	—	—	—	—	(5)	(5)
Net loss	—	—	—	—	—	(4,936)	—	(4,936)
Balance at June 30, 2025	—		1,261,290	$ —	$ 301,177	$ (273,852)	$ (11)	$ 27,314
Balance at December 31, 2025	—	$ —	1,261,685	$ —	$ 301,728	$ (283,137)	$ 1	$ 18,592
Stock-based compensation expense	—	—	—	—	12,898	—	—	12,898
Issuance of Series B redeemable convertible preferred stock in connection with the acquisition of Faeth Therapeutics	10,497	145,384	—	—	—	—	—	—
Fair value of the Assumed Options that relates to the pre-combination service period	—	—	—	—	452	—	—	452
Issuance of Series B redeemable convertible preferred stock in connection with private placement, net of issuance costs	14,440	183,092	—	—	—	—	—	—
Vesting of restricted stock shares	—	—	1,505	—	—	—	—	—
Exercise of options into common stock	—	—	77,143	—	1,033	—	—	1,033
Unrealized loss on marketable securities	—	—	—	—	—	—	(25)	(25)
Net loss	—	—	—	—	—	(170,236)	—	(170,236)
Balance at March 31, 2026	24,937	328,476	1,340,333	—	316,111	(453,373)	(24)	(137,286)
Stock-based compensation expense	—	—	—	—	4,483	—	—	4,483
Conversion of Series B redeemable convertible preferred stock into common shares	(24,435)	(321,709)	24,435,594	2	321,707	—	—	321,709
Exercise of stock options into common stock	—	—	57,042	—	98	—	—	98
Unrealized loss on marketable securities	—	—	—	—	—	—	(39)	(39)
Net loss	—	—	—	—	—	(16,007)	—	(16,007)
Balance at June 30, 2026	502	$ 6,767	25,832,969	$ 2	$ 642,399	$ (469,380)	$ (63)	$ 172,958

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

FAETH THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (186,243)	$ (11,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	17,381	725
Depreciation and amortization	54	62
Accretion on marketable securities	(1,126)	(442)
Non-cash lease expense	770	770
Amortization of financing lease right-of-use assets	1	9
Acquired in-process research and development from the acquisition of Faeth Therapeutics	132,957	—
Loss on asset disposal	—	20
Changes in operating assets and liabilities:		
Prepaid expenses	10,360	(354)
Other assets	138	28
Accounts payable and accrued liabilities	247	(113)
Compensation and employee benefits	(108)	(1,107)
Operating lease liabilities	(837)	(801)
Net cash used in operating activities	(26,406)	(13,003)
Cash flows from investing activities		
Purchases of property and equipment	(6)	(16)
Purchases of short-term investments	(158,560)	(8,786)
Maturities of short-term investments	12,600	24,500
Proceeds from sale of property and equipment	—	250
Net cash assumed in the acquisition of Faeth Therapeutics	6,464	—
Net cash (used in) provided by investing activities	(139,502)	15,948
Cash flows from financing activities		
Principal payments for financing leases	(80)	(525)
Proceeds from the sale of financing lease assets	—	142
Proceeds from issuance of Series B redeemable convertible preferred stock	200,000	—
Issuance costs from the private placement issuance of Series B redeemable convertible preferred stock	(16,908)	—
Payment of employee restricted stock tax withholdings	—	(3)
Employee stock purchase plan proceeds	—	5
Cash in lieu of fractional shares for reverse stock split	—	(1)
Exercise of options into common stock	1,131	—
Net cash provided by (used in) financing activities	184,143	(382)
Net increase in cash and cash equivalents	18,235	2,563
Cash and cash equivalents at beginning of period	8,668	9,994
Cash and cash equivalents at the end of period	$ 26,903	$ 12,557
Supplemental disclosure of noncash financing information:		
Fair value of Series B redeemable convertible preferred stock issued for the acquisition of Faeth Therapeutics	$ 145,384	$ —
Net assets acquired in the acquisition of Faeth Therapeutics	$ 12,879	$ —
Conversion of Series B Preferred Stock to Common Stock	$ 321,709	$ —

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

FAETH THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. ORGANIZATION AND OPERATIONS

Business

Faeth Therapeutics, Inc. (formerly known as Sensei Biotherapeutics, Inc.) (the "Company"), a clinical-stage biotechnology company, was originally incorporated in Maryland in 1999 and subsequently reincorporated in Delaware on December 1, 2017.

On February 17, 2026, the Company acquired Faeth Holdings Therapeutics, Inc. ("Faeth HoldCo") and its wholly owned subsidiary Faeth Therapeutics, LLC ("Faeth Subsidiary" and, together with Faeth HoldCo, "Legacy Faeth") pursuant to an Agreement and Plan of Merger (the "Merger Agreement"), dated as of February 17, 2026, by and among the Company, its merger subsidiaries and Legacy Faeth (such transaction, the "Acquisition").

Effective June 15, 2026, the Company changed its name from Sensei Biotherapeutics, Inc. to Faeth Therapeutics, Inc. The Company is focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways.

Liquidity and capital resources

Since its inception, the Company has devoted substantially all of its resources to advancing development of its portfolio of programs, establishing and protecting its intellectual property, conducting research and development activities, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Since its inception, the Company has incurred substantial losses and had a net loss of $186.2 million for the six months ended June 30, 2026. As of June 30, 2026, the Company had an accumulated deficit of $469.4 million. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future.

The Company will need additional financing to support its continuing operations and pursue its current strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company’s financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

The Company expects that its cash, cash equivalents and marketable securities as of June 30, 2026 of $186.4 million will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these financial statements. In February 2026, the Company completed a private placement financing through the sale of Series B Non-Voting Redeemable Convertible Preferred Stock (the "Series B Preferred Stock"), resulting in gross proceeds of $200 million.

On June 10, 2026, the Company obtained stockholder approval for the automatic conversion of its Series B Preferred Stock into Common Stock in accordance with Nasdaq listing rules. On June 15, 2026, 24,435.594 shares of Series B Preferred Stock automatically converted into an aggregate of 24,435,594 shares of Common Stock. Such converted shares were thereafter retired and, as a result, 24,435.594 shares resumed the status of authorized but unissued shares of preferred stock.

Pursuant to the terms of the Certificate of Designation (as defined below), conversion is subject to beneficial ownership limitations that prevent any holder from converting shares if such conversion would result in the holder and its affiliates beneficially owning more than 9.99% of the Company’s outstanding Common Stock. As of June 30, 2026, 501.899 shares of Series B Preferred Stock remain outstanding as a result of these blocker provisions. These remaining shares will convert into shares of Common Stock from time to time as holders sell down their positions or otherwise remain below their applicable beneficial ownership limitations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States ("US GAAP"). The condensed consolidated financial statements include those accounts of the Company and its subsidiaries after elimination of all intercompany accounts and transactions. Certain reclassifications have been made to amounts presented in our condensed consolidated statements of operations and comprehensive loss for the period ended June 30, 2025 to conform to the presentation for the period ended June 30, 2026.

Unaudited Interim Financial Information

The condensed consolidated financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). The accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal, recurring adjustments, that are necessary for a fair presentation of the financial position, results of operations, statement of stockholders' equity, and cash flows for the interim periods presented. Certain information and note disclosures normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted from these condensed consolidated financial statements, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The results for any interim period are not necessarily indicative of results for any future period.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods presented. Estimates are used for, but are not limited to, stock-based compensation, accrued research and development expenses, depreciation of equipment, fair value of financial instruments, contingencies, and the valuation of consideration transferred in the acquisition of Faeth Therapeutics. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits, commercial paper, corporate bonds, and investments in money market funds with commercial banks and financial institutions. As of June 30, 2026, cash and cash equivalents included cash on deposit at commercial banks and a money market fund that invests in U.S. Government securities.

Marketable Securities

Investments consist of marketable securities with original maturities greater than 90 days at the date of purchase. The Company has classified its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable securities to be available-for-sale. Accordingly, these investments are recorded at fair value (Level 2). Unrealized gains and losses are reported as the accumulated other comprehensive items in stockholders' equity. Amortization and accretion of premiums and discounts are recorded in other income (expense). Realized gains or losses on debt securities are included in interest income or interest expense, respectively. If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is other than temporary and, if so, marks the investment to market on the Company's statement of operations and comprehensive loss.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized over the estimated useful lives of the assets. Repairs or maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Office equipment and furniture	3—7 years
Research equipment	1—7 years

Leasehold improvements are depreciated over the shorter of their useful life or the life of the lease.

Acquired In-Process Research and Development Expense

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which include certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in process research and development ("IPR&D"). Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as research and development expense as of the acquisition date.

Redeemable Convertible Preferred Stock

The Company has classified its redeemable convertible preferred stock as temporary equity in the accompanying balance sheets due to redemption provisions that are outside of the control of the Company. Subsequent adjustments of the carrying values to the redemption values will be made only when it becomes probable that such a change in control event will occur. The Company did not accrete the carrying values of the redeemable convertible preferred stock to the redemption values as redemption was contingent on shareholder approval, which was obtained on June 10, 2026.

Preferred Stock Warrants

The Company accounts for its redeemable convertible preferred share warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the balance sheet as a long-term liability at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants are no longer considered a liability.

Segments

The Company manages its operations as a single segment, dedicated to improving outcomes for cancer patients by developing novel therapeutics, including through multi-node inhibition of critical oncogenic pathways. The Company's Chief Operating Decision Maker ("CODM"), the Chief Executive Officer ("CEO"), reviews the operating results on an aggregate basis and manages the operations as a single operating segment. The CODM oversees performance assessment and resource allocation by reviewing net loss as reported in the Company's consolidated statement of operations to guide operational decisions, strategic planning, and forecasting for future periods. To support this oversight, operating expenses are closely tracked to compare budget against actual results. As a single reporting segment, the significant operating expense categories regularly provided to the CODM include research and development, and general and administrative expenses. These expense categories are reported as separate line items in the Company's consolidated statements of operations. All segment assets are reflected as 'total assets' in the consolidated balance sheet. All equipment, leasehold improvements, and fixed assets are located in the United States, and agreements with partners are denominated in U.S. dollars, unless otherwise noted.

Leases

At lease inception, the Company determines if an arrangement is or contains a lease, and if so, assesses the lease for classification as either an operating or finance lease. A lease is classified as a finance lease if any one of the following criteria are met: (i) the lease transfers ownership of the asset by the end of the lease term, (ii) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (iii) the lease term is for a major part of the remaining useful life of the asset, (iv) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset, or (v) the leased asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease. A lease is classified as an operating lease if it does not meet any of these criteria.

Leases with a term greater than one year are recognized on the balance sheet as right-of-use ("ROU") assets and current and non-current lease liabilities, as applicable. Leases with a term of one year or less are expensed as rent in the period incurred. The Company elected not to separate lease and non-lease components for all underlying assets. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate is determined by using the rate of interest that

the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. Lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the options. For leases that existed prior to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASC 842"), the Company used the remaining lease term to determine the appropriate incremental borrowing rate.

Recently Issued Accounting Standards

In November 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* The standard is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the impact this standard will have on its condensed consolidated financial statements.

3. ACQUISITION OF FAETH AND PIPE ISSUANCE

On February 17, 2026, the Company acquired Faeth Therapeutics pursuant to the Merger Agreement.

Under the terms of the Merger Agreement, the Company issued to the stockholders of Faeth an aggregate of 10,497.0980 shares of Series B Preferred Stock, par value $0.0001 per share, representing 10,497,098 shares of common stock of the Company, par value $0.0001 per share ("Common Stock"), on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations. The outstanding warrant to purchase shares of Faeth Subsidiary capital stock was converted into a warrant to purchase an aggregate of 2.1020 shares of Series B Preferred Stock, representing a warrant to purchase 2,102 shares of Common Stock on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations. In addition, all outstanding options to purchase Faeth Subsidiary common stock were assumed by the Company and were converted into options to purchase an aggregate of 252,210 shares of Common Stock (the "Assumed Options"). In connection with the Acquisition, stock options to purchase 6,338,670 shares of Faeth common stock, held by certain Faeth employees, were immediately exercised by the Faeth employees, of which 4,273,182 options had their vesting accelerated. Faeth HoldCo paid $15.6 million to cover tax liabilities created by such exercise of the options.

Concurrently with the acquisition of Faeth Therapeutics, on February 17, 2026, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with new and returning investors to raise $200.0 million of gross proceeds in which investors were issued an aggregate of 14,440.395 shares of Series B Preferred Stock, or 14,440,395 on an as-converted-to-common basis (without giving effect to any beneficial ownership limitations) at a price of $13,850 per share, or $13.85 per share on an as-converted-to-common basis, (collectively, the "2026 Private Placement"). The 2026 Private Placement closed on February 20, 2026.

Following the receipt of stockholder approval on June 10, 2026, each share of Series B Preferred Stock automatically converted into 1,000 shares of Common Stock, subject to certain beneficial ownership limitations established by each holder (pursuant to which 501.899 shares of Series B Preferred Stock remain unconverted as of June 30, 2026). As a result of the transactions, equityholders of the Company immediately prior to the acquisition owned approximately 4.9% of the Common Stock, equityholders of Faeth Therapeutics immediately prior to the acquisition owned approximately 40.6% of the Common Stock, and investors in the 2026 Private Placement owned approximately 54.5% of the Common Stock, in each case, calculated on a fully-diluted, as-converted-to-common basis (without giving effect to any beneficial ownership limitations) using the treasury stock method and based on the implied equity values of the Company and Faeth Therapeutics.

The Acquisition was accounted for as an asset acquisition with the Company as the accounting acquirer. Upon completion of the Acquisition and the 2026 Private Placement, the Company obtained control of Faeth's assets, consisting primarily of cash, prepayments of tax gross-up payments related to the accelerated vesting of options held by Faeth employees prior to the Acquisition, and acquired IPR&D. In accordance with Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"), under the asset acquisition method of accounting, the assets acquired and liabilities assumed are recognized and measured at fair value and no goodwill is recorded or recognized. Acquired IPR&D that has no future alternative use is expensed at the time of acquisition.

The estimated fair value of the consideration transferred of $145.8 million is summarized as follows (in thousands):

Assumed Options	$	452
Series B Preferred Stock		145,384
Total consideration transferred	$	145,836

The fair value of the consideration transferred was measured using the price per share the investors paid as part of the 2026 Private Placement. The Assumed Options reflects the portion of the acquisition date fair-value based measure that relates to the pre-combination service period.

The following table summarizes the allocation of the estimated fair value of the consideration transferred to the net assets acquired by the Company (in thousands):

Assets acquired:		
Cash and cash equivalents	$	6,464
Prepaid expenses		11,487
Other current assets		554
Property and equipment, net		10
Other non-current assets		412
Total assets acquired		18,927
Liabilities assumed:		
Accounts payable and accrued liabilities		5,844
Compensation and employee benefits liabilities		204
Total liabilities assumed		6,048
Net assets acquired	$	12,879
In-process research and development		132,957
Total consideration transferred	$	145,836

The Company recognized $4.8 million of research and development expenses and $6.2 million of general and administrative expenses related to the accelerated vesting of 4,273,182 options held by Faeth employees prior to the Acquisition during the six months ended June 30, 2026.

The Company recognized $9.1 million of research and development expenses and $6.5 million of general and administrative expenses for tax gross-up payments related to the vesting of these options. The Company acquired $11.4 million of prepaid expenses related to the tax gross-up payments included in the net assets acquired by the Company, which were recognized as expense during the six months ended June 30, 2026. The tax gross-up payments are not in scope for accounting under ASC 718 and are recognized in the period in which they are incurred.

For the Assumed Options that were not vested as of the Acquisition, the Company recognized $0.7 million and $0.1 million of general and administrative and research and development expenses respectively during the six months ended June 30, 2026.

4. MARKETABLE SECURITIES

Marketable securities consist of the following as of June 30, 2026 and December 31, 2025 (in thousands):

	As of June 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 142,108	$ —	$ (59)	$ 142,049
Corporate bonds	17,493	—	(4)	17,489
Total	$ 159,601	$ —	$ (63)	$ 159,538

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 9,772	$ 1	$ (1)	$ 9,772
Corporate bonds	2,743	1	-	2,744
Total	$ 12,515	$ 2	$ (1)	$ 12,516

As of June 30, 2026, all marketable securities held by the Company had remaining contractual maturities of one year or less.

There were no impairments of the Company's assets measured and carried at fair value during the six months ended June 30, 2026 and 2025.

As of June 30, 2026, an immaterial amount of unrealized losses were associated with marketable securities with contractual maturities of one year or less.

5. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair value measurements as of June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 24,389	$ —	$ —	$ 24,389
Marketable Securities:				
Commercial paper	—	142,049	—	142,049
Corporate bonds	—	17,489	—	17,489
Total	$ 24,389	$ 159,538	$ -	$ 183,927
Liabilities:				
Preferred stock warrant liability	$ -	$ -	$ 1	$ 1
Total financial liabilities	$ -	$ -	$ 1	$ 1

	Fair value measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 7,896	$ —	$ —	$ 7,896
Marketable Securities:				
Commercial paper	—	9,772	—	9,772
Corporate bonds	—	2,744	—	2,744
Total	$ 7,896	$ 12,516	$ —	$ 20,412

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

There were no transfers among Level 1, Level 2 or Level 3 categories in the six months ended June 30, 2026 and 2025.

Preferred Stock Warrant Liability

In September 2021, Faeth issued 10,550 warrants (the "Warrants") to Western Alliance Bank ("Western Alliance") to purchase shares of redeemable convertible Preferred Stock, at an exercise price of $1.42177. Western Alliance can exercise the Warrants until the termination of the agreement on September 6, 2031. Under the terms of the Merger Agreement, the Warrants were converted into warrants to purchase 2.1020 shares of Series B Preferred Stock. No Warrants were exercised as of June 30, 2026.

The Company concluded that the Warrants required liability classification based on the guidance in ASC 480. The Warrants were recorded at fair value using the Black-Scholes method with the following inputs:

	For the six months ended June 30, 2026
Expected equity volatility	60%
Risk-free interest rate	3.54%
Expected term (years)	1.5

The following table presents a roll-forward of the aggregate fair values of the Preferred Stock Warrant Liability (in thousands):

	Preferred Stock Warrant Liability
Balance as of February 17, 2026	$ 1
Change in fair value	-
Balance as of June 30, 2026	$ 1

6. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2026	December 31, 2025
Research equipment	$ 12	$ —
Office equipment and furniture	385	369
Leasehold improvement	253	253
Total property and equipment	650	622
Less accumulated depreciation and amortization	(606)	(540)
Property and equipment, net	$ 44	$ 82

Depreciation and amortization expense for the six months ended June 30, 2026 and 2025 was $54 thousand and $62 thousand, respectively.

During the six months ended June 30, 2025, the Company disposed of all research equipment through the sale of fixed assets, resulting in a reduction of the gross carrying amount to zero. The related accumulated depreciation of $1,078 thousand was written off in connection with this disposal. A gain of $23 thousand was recognized on the sale and is included in the other income (expense) line in the condensed consolidated statements of operations and comprehensive loss for the period.

7. COMMITMENTS AND CONTINGENCIES

Operating Leases

As of June 30, 2026, the Company leases office and laboratory facilities under operating leases, which expire at various dates through 2027. The Company has $0.7 million in letters of credit outstanding as security on certain of these leases. As part of its adoption of ASC 842, the Company recorded operating ROU assets and operating lease liabilities for these leases as of January 1, 2022. The Company elected the short-term lease recognition exemption for operating leases with an initial term of less than 12 months and therefore did not recognize the lease on the Company's balance sheet. Rent expense was recognized on a straight-line basis over the lease term. Short-term lease expense for the six months ended June 30, 2026 and 2025 was $0.1 million and immaterial, respectively.

Finance Leases

The Company previously leased research equipment and furniture under finance leases, which were disposed of or reached the end of their terms during the six months ended June 30, 2026.

The following table contains a summary of the lease costs recognized under ASC 842 pertaining to the Company's finance and operating leases for the six months ended June 30, 2026 (in thousands):

	For the Six Months Ended June 30,	
	2026	2025
Lease cost:		
Amortization of finance ROU assets	$ 1	$ 9
Interest on finance lease liabilities	1	23
Operating lease cost	806	866
Variable lease cost	439	428
Total lease costs	$ 1,247	$ 1,326

During the six months ended June 30, 2025, the Company disposed of research equipment classified as a ROU asset under a lease agreement. The ROU asset was sold, resulting in a loss of $43 thousand, which is included in the other income (expense) line in the condensed consolidated statements of operations and comprehensive loss for the period.

The following table contains a summary of other information pertaining to the Company's finance and operating leases for the three and six months ended June 30, 2026 and 2025 (in thousands, except lease term and discount rate):

	For the Six Months Ended June 30,	
	2026	2025
Other lease information:		
Operating cash outflows for operating leases	$ 873	$ 897
Operating cash outflows for finance leases	$ 1	$ 23
Financing cash outflows from finance leases	$ 80	$ 525
Weighted-average remaining lease term:		
Operating leases	0.4 years	1.4 years
Financing leases	-- years	0.7 years
Weighted-average discount rate:		
Operating leases	7.6%	7.6%
Financing leases	--%	10.0%

The following table presents the maturity of the Company's operating and finance lease liabilities as of June 30, 2026 (in thousands):

	Operating	Financing
2026 (Remainder of 2026)	$ 540	$ —
2027	59	—
Total future minimum lease payments	599	—
Less: imputed interest	7	—
Total lease liabilities	$ 592	$ —

License Agreements

In connection with the Acquisition, the Company assumed the following licensing agreements, each originally entered into by Faeth, to obtain the right to make, use, and sell licensed products currently in development.

Cornell University

In June 2020, Faeth entered into a license agreement (the "Cornell Agreement") with Cornell University ("Cornell"), pursuant to which Faeth was granted an exclusive, sublicensable, royalty-bearing license to develop and commercialize products using the licensed combination therapy for PI3K associated diseases and disorders. In connection with the Acquisition, the Company assumed all of Faeth's rights and obligations under the Cornell Agreement. As consideration for the Cornell Agreement, the Company agreed to pay annual license fees of $0.1 million on the anniversary of the agreement. The license fees are recorded as research and development expense in the statements of operations and comprehensive loss as the acquired license represents in-process research and development with no alternative future use. Under the Cornell Agreement, the Company is required to pay up to an aggregate of $6.2 million upon the achievement of certain development and commercial milestones. The Company is also required to pay royalties to Cornell in the low to mid single digit percentage range based on net sales of licensed products. The development milestone payment will be recorded when the milestone is achieved, and the commercial milestone payment and royalties will be recorded when the sales

occur. During the six months ended June 30, 2026, payments of $0.1 million were made for annual fees. As of June 30, 2026, no milestones were achieved.

Cancer Research Technology Limited (CRT)

In June 2020, Faeth entered into a license agreement (the "CRT Agreement") with Cancer Research Technology Limited ("CRT"), who is wholly owned by Cancer Research UK, pursuant to which Faeth was granted an exclusive, sublicensable, royalty-bearing license to develop and commercialize Non-Essential Amino Acid Restriction ("NEAAR", formerly FTH-002), or other products with dietary modulation of amino acids. In connection with the Acquisition, the Company assumed all of Faeth's rights and obligations under the CRT Agreement. As consideration for the CRT Agreement, the Company paid an upfront fee of £0.1 million in 2020 which was recorded as research and development expense in the statements of operations and comprehensive loss as the acquired license represents in-process research and development with no alternative future use. Under the CRT Agreement, the Company is required to pay up to an aggregate of £7.9 million related to the achievement of certain development and commercial milestones and up to an aggregate of £18.1 million related to the achievement of certain partnership milestones. In addition, the Company is required to pay royalties to CRT in the low to mid single-digit percentage range based on net sales of licensed products and sublicense royalty fees in the low double-digit percentage range for any revenue derived from sublicensing. The development milestone payment will be recorded when the milestone is achieved, and the commercial milestone payment, royalties, and sublicense revenues will be recorded when the sales occur. As of June 30, 2026, no milestones have been achieved.

Ravenna Pharmaceuticals (Takeda)

In February 2021, Faeth entered into an agreement with Ravenna Pharmaceuticals, Inc. (the "Ravenna Agreement"), pursuant to which Faeth was granted intellectual property and existing data and agreements to develop and commercialize serabelisib (formerly FTH-001) and sapanisertib (formerly FTH-003) in exchange for an upfront fee of $0.5 million. In connection with the Acquisition, the Company assumed all of Faeth's rights and obligations under the Ravenna Agreement. The upfront payment was recorded as research and development expense in the statements of operations and comprehensive loss because the acquired assets represented in-process research and development with no alternative future use.

As part of the Ravenna Agreement, the Company assumed a license agreement with Takeda that was originally entered into in March 2019 between Takeda Pharmaceutical Company Limited and Petra Pharma Corporation, which was subsequently assigned to Ravenna Pharmaceuticals, Inc. (the "Takeda Agreement") pursuant to which the Company is required to pay up to an aggregate of $124.0 million related to the achievement of certain development and commercial milestones. The Company is also required to pay royalties to Takeda in the low to mid-single-digit percentage range based on net sales of licensed products. The development milestone payment will be recorded when the milestone is achieved, and the commercial milestone payment, royalties, and sublicense revenues will be recorded when the sales occur. As of June 30, 2026, no milestones have been achieved.

As additional consideration under the Takeda Agreement, the Company was required to issue up to $15.0 million in equity to Takeda upon the first dosing in a Phase 3 clinical trial. In January 2026, this provision was renegotiated and removed in its entirety.

Calithera Biosciences (Millennium Takeda)

In May 2023, Faeth entered into a purchase agreement (the "Calithera Agreement") with Calithera Biosciences ("Calithera") under which Faeth was granted intellectual property and existing data and agreements to develop and commercialize serabelisib and sapanisertib. In connection with the Acquisition, the Company assumed all of Faeth's rights and obligations under the Calithera Agreement. As consideration for the Calithera Agreement, the Company paid an upfront fee of $0.4 million. The payments were recorded as research and development expense in the statements of operations and comprehensive loss because the acquired assets represented in-process research and development with no alternative future use.

As part of the Calithera Agreement, the Company assumed existing license agreements with the Regents of the University of California (the "University of California Agreement") and Millennium Pharmaceuticals (the "Millennium Agreement"). Under the University of California Agreement, the Company is required to pay up to an aggregate of $1.0 million per licensed product related to the achievement of certain development and commercial milestones, of which $0.8 million remains unpaid as of June 30, 2026. The Company is also required to pay tiered low single-digit royalties based on net sales of licensed products and a low double-digit percentage based on sublicense income if the Company sublicenses the rights granted under the University of California Agreement. Under the Millennium Agreement, the Company is required to pay up to an aggregate of $119.0 million in development, regulatory and commercial launch milestone payments and up to an aggregate of $250.0 million in sales milestone payments. The Company is also required to pay tiered single-digit royalties based on annual net sales of licensed products. Under both agreements, the

development milestone payment will be recorded when the milestone is achieved, and the commercial milestone payment and royalties will be recorded when the sales occur. As of June 30, 2026, no milestones have been achieved under either agreement.

Litigation

The Company records estimated losses from loss contingencies, such as a loss arising from litigation, when it determines that it is probable a liability has been incurred and the amount of loss can be reasonably estimated. Litigation is subject to many factors that are difficult to predict so that there can be no assurance, in the event of a material unfavorable result in one or more claims, the Company will not incur material costs.

8. ACCOUNTS PAYABLE AND CURRENT ACCRUED EXPENSES

Accounts payable and accrued liabilities consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Accounts payable	$ 2,147	$ 689
Accrued expenses	5,251	715
Other current liabilities	175	77
Total	$ 7,573	$ 1,481

9. REDEEMABLE CONVERTIBLE PREFERRED STOCK

In conjunction with the Merger Agreement, on February 17, 2026, the Board of Directors of the Company (the "Board of Directors") adopted the Certificate of Designation, which authorized the issuance of 25,045 shares of Series B Preferred Stock, par value of $0.0001 per share.

Under the terms of the Merger Agreement, the Company issued to the stockholders of Faeth an aggregate of 10,497.0980 shares of Series B Preferred Stock, representing 10,497,098 shares of Common Stock on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations.

Concurrently with the Acquisition, the Company entered into the Purchase Agreement with new and returning investors to raise $200.0 million of gross proceeds in which investors were issued an aggregate of 14,440.395 shares of Series B Preferred Stock, or 14,440,395 on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations, at a price of $13,850 per share, or $13.85 per share on an as-converted-to-common basis. The 2026 Private Placement closed on February 20, 2026.

On June 10, 2026, the Company obtained stockholder approval of (i) the conversion of the Series B Preferred Stock into shares of Common Stock, (ii) the change of control under Nasdaq listing rules, and (iii) the amendment of the Company's certificate of incorporation to increase authorized shares of Common Stock to 300,000,000 (collectively, the "Company Stockholder Matters"), and on June 15, 2026, 24,435.594 shares of Series B Preferred Stock automatically converted into 24,435,594 shares of Common Stock. Pursuant to the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Redeemable Convertible Preferred Stock (the "Certificate of Designation"), conversion of the Series B Preferred Stock is subject to beneficial ownership limitations established by each holder. As of June 30, 2026, 501.899 shares of Series B Preferred Stock remain outstanding as a result of these beneficial ownership limitations and continue to be classified in temporary equity.

The holders of Preferred Stock have the following rights, preferences and privileges:

Voting Rights

Holders of the Series B Preferred Stock have no voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the majority of outstanding shares of Series B Preferred Stock (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (ii) issue further shares of Series B Preferred Stock or increase or decrease the number of authorized shares of Series B Preferred Stock, (iii) consummate either a merger or consolidation or other business combination in which stockholders of the Company do not hold at least a majority of the voting power, or (iv) authorize or issue any class or series of stock that has powers, preferences or rights that are senior to those of the Series B Preferred Stock.

Dividends

Holders of outstanding shares of Series B Preferred Stock are entitled to receive dividends on shares of Series B Preferred Stock, on an as-converted basis to common stock, equal to and in the same form and manner as dividends paid on shares of common stock.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the corporation, the holders of shares of the Series B Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series B Preferred Stock were fully converted to common stock and amounts shall be paid pari passu with all holders of Common Stock, plus an additional amount equal to any dividends declared on but unpaid to such shares.

Redemption

The Series B Preferred Stock does not have redemption rights. However, if the Company had failed to obtain shareholder approval within six months of the initial issuance of Series B Preferred Stock, shares of Series B Preferred Stock would have become eligible for cash settlement at the option of the holder for a fair value equal to the closing price of the Company's common stock on the last trading day prior to the date that the notice for cash settlement is delivered from the holder to the Company.

Conversion

Each share of Series B Preferred Stock automatically converted at a conversion ratio of 1,000 shares of common stock for each share of Series B Preferred Stock on June 15, 2026, which was the third business day after stockholder approval of the Company Stockholder Matters.

10. EQUITY

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors.

Common Stock Warrants

There was no common stock warrant activity related to common stock warrants issued in conjunction with equity and debt fundraising events for the six months ended June 30, 2026. The following is a summary of the common stock warrants outstanding at June 30, 2026 and December 31, 2025:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	1,143	$ 2,185.04	3.15	$ —
Outstanding at June 30, 2026	1,143	$ 2,185.04	2.66	$ —

11. STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

The Company's 2018 Stock Incentive Plan (the "2018 Plan") provided for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. Upon the effectiveness of the 2021 Plan (as defined below), the Company ceased issuing new awards under the 2018 Plan.

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the "2021 Plan") became effective in February 2021. The 2021 Plan provided for the grant of incentive stock options to employees, including employees of any parent or subsidiary corporations, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. Upon the effectiveness of the 2026 Plan (as defined below) on June 10, 2026, the Company ceased issuing new awards under the 2021 Plan.

2026 Equity Incentive Plan

The 2026 Equity Incentive Plan (the "2026 Plan") became effective on June 10, 2026 upon approval by the Company's stockholders. The 2026 Plan provides for the grant of incentive stock options to employees, including employees of any parent or subsidiary corporations, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. The number of shares initially reserved for issuance under the 2026 Plan was 2,671,981 shares, which will automatically increase on January 1 of each calendar year, starting on January 1, 2027 through January 1, 2036, in an amount equal to 5.0% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board of Directors. As of June 30, 2026, 2,376,981 shares remained available for issuance pursuant to the 2026 Plan.

Accelerated Options From The Acquisition

On February 17, 2026, in connection with the Acquisition, stock options to purchase 6,338,670 shares of Faeth common stock, held by certain Faeth employees, were immediately exercised by the Faeth employees, of which 4,273,182 options had their vesting accelerated (the "Accelerated Options"). The modification of the terms that resulted in the immediate vesting of the Accelerated Options was executed in contemplation of the Acquisition and did not require continued employment or future service by the option holders. The Company recognized $4.8 million of research and development expenses and $6.2 million of general and administrative expenses upon the Acquisition representing the fair value of the Accelerated Options on the date of the modification.

Assumed Options From The Acquisition

On February 17, 2026, in connection with the Acquisition, the Company assumed all outstanding and unexercised stock options to purchase an aggregate of 252,210 shares of common stock. The Assumed Options were converted into options to purchase shares of the Company's common stock using an exchange ratio of approximately 0.1993, with exercise prices ranging from $1.16 to $5.22 per share on an as-converted basis. The Company recognized $0.5 million representing the fair value of the Assumed Options attributable to the pre-combination service period as part of the consideration transferred. The remaining unrecognized compensation expense associated with the unvested Assumed Options will be recognized over their remaining service periods, which range from approximately 0.1 to 3.5 years. See Note 3 for additional information regarding the Acquisition.

Inducement Grants

In connection with the Acquisition, the Company granted inducement nonstatutory stock options to purchase an aggregate of 2,319,891 shares of common stock to former Faeth employees on February 19, 2026, at an exercise price of $27.22 per share, as a material inducement to entering employment with the Company. In addition, on March 11, 2026, the Company granted an inducement nonstatutory stock option to purchase 166,435 shares of common stock at an exercise price of $29.37 per share to a new employee as a material inducement to entering employment with the Company. These stock options will vest over a four-year period, with 25% of the shares underlying each option award vesting on the one-year anniversary of the applicable employees' new hire date and the remaining 75% of the shares underlying each option award vesting monthly thereafter for three-years. Vesting of each option award is subject to such employee's continued service with the Company through the applicable vesting dates. These stock options were granted outside of the 2021 Plan as an inducement material to each employee's acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

2026 Inducement Plan

On April 10, 2026, the Board of Directors adopted the 2026 Inducement Plan, which provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to new employees as a material inducement to entering employment with the Company. A total of 450,000 shares of common stock are reserved for issuance under the 2026 Inducement Plan. The 2026 Inducement Plan was adopted without stockholder approval in accordance with Nasdaq Listing Rule 5635(c)(4). During the six months ended June 30, 2026, the Company granted

nonstatutory stock options to purchase an aggregate of 199,650 shares of common stock under the 2026 Inducement Plan. As of June 30, 2026, 250,350 shares remained available for issuance pursuant to the 2026 Inducement Plan.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") became effective in February 2021. A total of 16,666 shares (333,333 prior to the 1-for-20 reverse stock split of the Company's issued and outstanding shares of common stock effected on June 16, 2025) of common stock were initially reserved for issuance under the 2021 ESPP. As of June 30, 2026, the Company had issued 12,220 shares under the 2021 ESPP, no shares were issued in six months ended June 30, 2026. Upon the effectiveness of the 2026 ESPP (as defined below) on June 10, 2026, the Company ceased issuing new awards under the 2021 ESPP.

2026 Employee Stock Purchase Plan

The 2026 Employee Stock Purchase Plan (the "2026 ESPP") became effective on June 10, 2026 upon approval by the Company's stockholders. A total of 267,198 shares of common stock were initially reserved for issuance under the 2026 ESPP, which will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 through January 1, 2036, by an amount equal to the lesser of (i) 1.0% of the total shares of common stock outstanding on December 31 of the preceding calendar year and (ii) 534,396 shares, or a lesser number of shares determined by the Board of Directors. The purchase price of the shares under the 2026 ESPP is 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase date. As of June 30, 2026, no shares had been issued under the 2026 ESPP.

Stock Options

The Company granted options to purchase shares of common stock at a weighted average grant date fair value of $21.04 per share during the six months ended June 30, 2026, including grants under the 2021 Plan, the 2026 Plan, the 2026 Inducement Plan, and inducement grants outside any plan. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the stock options on the applicable grant dates.

The following is a summary of option activity for employee awards under the 2018 Plan, the 2021 Plan, the 2026 Plan, the 2026 Inducement Plan, inducement grants outside any plan and the assumed options for the six months ended June 30, 2026:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	272,244	$ 80.56	6.98	$ 138
Granted	3,107,976	$ 27.06		
Assumed Options	252,210	$ 1.34		
Exercised	(134,185)	$ 8.42		
Forfeited	(39,374)	$ 12.85		
Expired	(10,130)	$ 150.58		
Outstanding at June 30, 2026	3,448,741	$ 29.93	9.39	$ 6,478
Vested or expected to vest as of June 30, 2026	3,448,741	$ 29.93	9.39	$ 6,478
Exercisable at June 30, 2026	182,672	$ 103.25	4.25	$ 1,618

The aggregate intrinsic value of the outstanding stock option awards is calculated as the difference between the exercise price and the market price of the Company's common stock at June 30, 2026. The aggregate intrinsic value of stock options exercised in the six months ended June 30, 2026 was $2.2 million and there were no option exercises for the six months ended June 30, 2025.

The grant date fair value of options vested during the six months ended June 30, 2026 and 2025 was $1.1 million and $0.7 million, respectively.

At June 30, 2026, there was $62.2 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 3.58 years.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions.

The following is a summary of the restricted stock unit activity during the six months ended June 30, 2026:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2025	2,136	$ 52.17
Vested	(1,505)	$ 62.05
Forfeited	(489)	$ 28.60
Unvested at June 30, 2026	142	$ 28.60

Pursuant to the 2021 Plan, the Company has historically granted restricted stock units which vest annually over a period of one, two, three or four years. The Company granted no restricted stock units during the six months ended June 30, 2026.

As of June 30, 2026, unrecognized stock-based compensation expense associated with the restricted stock units was immaterial and is expected to be recognized over a weighted-average period of 0.63 years.

Common Stock Warrants

The following is a summary of the common stock warrant activity during the six months ended June 30, 2026:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding and exercisable at December 31, 2025	229	$ 217.49	1.98	$ —
Outstanding and exercisable at June 30, 2026	229	$ 217.49	1.49	$ —

As of June 30, 2026 there was no unrecognized stock-based compensation expense associated with the common stock warrants.

For the six months ended June 30, 2026 and 2025, respectively, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options and common stock warrants granted. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	For the Six Months Ended June 30,	
	2026	2025
Volatility	95%-122%	94%-96%
Expected term (years)	2.3-6.1	5.5-6.0
Risk-free interest rate	3.5%-4.3%	4.2%-4.4%
Dividend rate	—%	—%

- Volatility—The Company lacks sufficient Company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to its own historical volatility and will continue to do so until it has adequate historical data regarding the volatility of its own traded stock price.
- Expected term—The Company calculates the expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience.
- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the condensed consolidated statements of operations for the three and six months ended June 30, 2026 and 2025 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 1,573	$ 82	$ 7,071	$ 208
General and administrative	2,910	182	10,310	517
Total stock-based compensation expense	$ 4,483	$ 264	$ 17,381	$ 725

12. EMPLOYEE RETIREMENT PLAN

The Company maintains a defined contribution 401(k) plan (the "Plan") for all employees. Under the Plan, participants may make voluntary contributions up to the maximum amount allowable by law. The Plan is based on employees' salary deferral, and the Company matches employees' contributions up to 4% of the employees' base salary. Employees are 100% vested in the Company's match contributions. During the three months ended June 30, 2026 and 2025, the Company's matching contributions were less than $0.1 million. During the six months ended June 30, 2026 and 2025, the Company's matching contributions were less than $0.1 million and $0.1 million, respectively.

13. COMPENSATION AND EMPLOYEE BENEFITS

Compensation and employee benefits consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Accrued incentive compensation	$ 889	$ 111
Accrued restructuring - compensation (Note 16)	342	1,159
Other compensation related liabilities	184	50
Total	$ 1,415	$ 1,320

14. INCOME TAXES

The Company recorded no provision for income taxes for the three and six months ended June 30, 2026 and 2025.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards, equity-based compensation, research and development tax credit carryforwards, and capitalized research and development expenditures. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the Company's otherwise recognizable net deferred tax assets.

15. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands, except share and per share amounts):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2026	2025	2026	2025
Net loss	$ (16,007)	$ (4,936)	$ (186,243)	$ (11,800)
Net loss per share—basic and diluted	$ (2.84)	$ (3.91)	$ (53.50)	$ (9.36)
Weighted-average shares outstanding, basic and diluted	5,643,222	1,260,867	3,481,149	1,260,202

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	For the Six Months Ended June 30,	
	2026	2025
Stock options to purchase common stock	3,448,741	295,349
Unvested restricted stock units	142	2,274
Warrants issued to employees and contractors to purchase common stock	229	229
Warrants issued related to convertible notes and other equity agreements	1,143	1,143
Series B redeemable convertible preferred stock	501,899	

16. RESTRUCTURING AND RELATED CHARGES

In November 2024, the Company announced a restructuring initiative to streamline operations and focus resources on advancing the clinical development of solnerstotug (the "2024 Restructuring"). As part of the 2024 Restructuring, the Company closed its research site in Rockville, Maryland, and reduced its workforce by approximately 46%, with the majority of reductions occurring in the preclinical research and development group. These actions were intended to extend the Company's cash runway.

In October 2025, the Company announced it was exploring strategic alternatives. In November 2025, the Company's Board of Directors approved a reduction in force of approximately 65% of the Company's workforce (together with the October 2025 actions, the "2025 Restructuring") to preserve capital while the Company evaluated potential mergers, asset sales, or other strategic transactions.

The 2024 Restructuring and 2025 Restructuring costs are primarily related to one-time termination benefits and ongoing benefit arrangements, both of which included severance payments and extended benefits coverage. Aggregate costs also included certain contract termination costs.

The following tables summarize the accrued liabilities activity recorded in connection with the 2024 Restructuring and 2025 Restructuring for the six months ended June 30, 2026 and 2025 respectively (in thousands):

	Personnel	Other	Total
Balance at December 31, 2025	$ 1,159	$ —	$ 1,159
Restructuring and other costs, net	-	-	-
Cash payments	(435)	—	(435)
Balance at March 31, 2026	724	—	724
Cash payments	(382)	—	(382)
Balance at June 30, 2026	$ 342	$ —	$ 342

	Personnel	Other	Total
Balance at December 31, 2024	$ 445	$ 31	$ 476
Restructuring and other costs, net	25	(2)	23
Cash payments	(346)	(16)	(362)
Balance at March 31, 2025	124	13	137
Restructuring and other costs, net	—	(3)	(3)
Cash payments	(124)	(6)	(130)
Balance at June 30, 2025	$ —	$ 4	$ 4

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

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words and phrases "designed to," "may," "might," "can," "will," "to be," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "likely," "continue," "ongoing" or similar expressions, or the negative of such words, are intended to identify "forward-looking statements." We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below in this Quarterly Report under the caption "Risk Factors," and in our other filings with the Securities and Exchange Commission, or SEC. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2025, which are included in our Annual Report on Form 10-K filed with the SEC on March 30, 2026.

Overview

We are a clinical-stage biotechnology company focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways. On February 17, 2026, we completed the acquisition of Faeth Therapeutics, a clinical-stage biotechnology company developing multi-node therapies targeting tumor metabolism and signaling (the "Acquisition"), and received $200 million in gross proceeds from the 2026 Private Placement from a broad syndicate of institutional investors. Effective June 15, 2026, we changed our corporate name from Sensei Biotherapeutics, Inc. to Faeth Therapeutics, Inc. The acquisition brought Faeth's lead asset, PIKTOR, a proprietary investigational all-oral combination of serabelisib and sapanisertib that inhibits multiple nodes of the PI3K/AKT/mTOR pathway, into our pipeline. For additional information regarding the terms of the acquisition and the concurrent financing, see Note 3 to the condensed consolidated financial statements.

Following the Acquisition, our lead program is PIKTOR, an oral multi-node inhibitor of the PI3K/AKT/mTOR pathway in development for endometrial and breast cancer. The PI3K/AKT/mTOR pathway is dysregulated in up to 50% of all solid tumors, making it one of the most prevalent therapeutic targets in oncology. Our core thesis is that simultaneously suppressing multiple pathway nodes can produce deeper, more durable tumor suppression than approved therapies that target only a single node. PIKTOR is currently being evaluated in an ongoing Phase 2 trial in second-line advanced endometrial cancer (Study FTH-PIK-201), with topline data anticipated by year-end. Additionally, in April 2026 the first patient was dosed in our Phase 1b/2 trial in HR+/HER2- advanced breast cancer (Study FTH-PIK-101), from which we expect to report interim data in 2027. We believe the $200 million in gross financing proceeds, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund operations through these key clinical milestones.

Prior to the Acquisition, we were primarily focused on the development of solnerstotug (formerly SNS-101), our conditionally active monoclonal antibody targeting the immune checkpoint VISTA. We are completing the remaining portion of the solnerstotug Phase 1/2 trial with patients currently on study.

We have incurred significant operating losses since our inception and expect to continue to incur losses for the foreseeable future. Our net loss was $186.2 million and $11.8 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $469.4 million and cash, cash equivalents and marketable securities of $186.4 million, which includes $183.1 million in net proceeds received in the 2026 Private Placement. The increase in our net loss for the six months ended June 30, 2026 compared to the same prior year period was primarily attributable to $133.0 million of acquired in-process research and development expense recognized in connection with the Acquisition, as well as increased research and development and general and administrative expenses resulting from the integration of Faeth's operations, including stock-based compensation expense related to the accelerated vesting of Faeth employee stock options and related tax gross-up payments.

Components of Our Results of Operations

Operating Expenses

Research and Development Expense

Our research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses include:

- expenses incurred under agreements with third-party contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- the cost of manufacturing our product candidates including the cost of third-party contract manufacturing organizations, or CMOs, that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- the cost of outsourced professional scientific development services;
- employee-related expenses, including salaries, bonuses, benefits and stock-based compensation, severance costs and other related costs for those employees engaged in the research and development function;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- fees for maintaining licenses and other amounts due under our third-party licensing agreements;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our direct external research and development expenses consist primarily of third-party costs, such as fees paid to CROs, CMOs, research/testing laboratories and outside consultants in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate these costs to specific product candidates because many of them are deployed across several of our development programs and, as such, are not separately classified. All other external research and development costs, including personnel costs, are not allocated to specific product candidates as they support multiple development programs. We have historically used internal resources primarily to conduct research and manage our preclinical development, process development, manufacturing and clinical development activities. These employees have worked across multiple development programs and, therefore, we have not historically tracked their costs by program and, as such, are not separately classified. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical studies, our current product candidates and any other product candidates we may acquire or develop;
- manufacturing of our product candidates or making arrangements with third-party manufacturers for both clinical and commercial supplies of these product candidates;
- successful patient enrollment in, and the initiation, duration and completion of clinical trials;
- the cost of gaining regulatory approvals for our product candidates, subject to the successful outcome of ongoing and future clinical trials; and
- the extent of any required post-marketing approval commitments to applicable regulatory authorities.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and significant additional development costs.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for legal, auditing and tax services, and insurance costs.

Acquired In-Process Research and Development Expense

Acquired in-process research and development expense represents the fair value of in-process research and development assets obtained in connection with asset acquisitions where the acquired IPR&D has no alternative future use as of the acquisition date. In accordance with ASC 805, such amounts are expensed at the time of acquisition rather than capitalized. We expect to recognize acquired IPR&D expense in periods in which we consummate acquisitions of development-stage assets. The amount and timing of such charges, if any, will depend on the nature, size and frequency of future acquisition activity.

Other Income (Expense)

Our other income (expense) consists of accretion on short-term investments, interest income (expense), gain or loss on fixed asset disposal, and changes in fair value of warrant liabilities.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Results of Operations

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

The following sets forth our results of operations for the three months ended June 30, 2026 and 2025:

(in thousands)	For the Three Months Ended June 30, 2026	2025	Change
Operating expenses:			
Research and development	$ 9,180	$ 2,533	$ 6,647
General and administrative	9,205	2,673	6,532
Total operating expenses	18,385	5,206	13,179
Loss from operations	(18,385)	(5,206)	(13,179)
Total other income	2,378	270	2,108
Net loss	$ (16,007)	$ (4,936)	$ (11,071)

Research and Development Expenses

Research and development expenses were $9.2 million for the three months ended June 30, 2026, compared to $2.5 million for the three months ended June 30, 2025. The increase of $6.6 million was primarily driven by development costs for PIKTOR which contributed approximately $5.0 million of research and development costs for the quarter, including preclinical, clinical trial, and chemistry, manufacturing and controls (or "CMC") related expenses, together with an increase of $2.3 million related personnel costs, including stock-based compensation and incentives. Legacy Sensei programs research and development spend was $0.7 million lower primarily due to lower expense associated with clinical trials.

General and Administrative Expenses

General and administrative expenses were $9.2 million for the three months ended June 30, 2026, compared to $2.7 million for the three months ended June 30, 2025. The increase of $6.5 million was primarily driven by $3.6 million of higher personnel costs, including stock-based compensation and incentives, $1.6 million of increased external administrative fees, $1.1 million of higher consulting expense and $0.2 million of higher licensing fees.

Other Income

Other income was $2.4 million for the three months ended June 30, 2026, compared to other income of $0.3 million for the three months ended June 30, 2025. The increase of $2.1 million was primarily related to an increase in interest income on securities.

Comparison of the Six Months Ended June 30, 2026 and 2025

The following sets forth our results of operations for the six months ended June 30, 2026 and 2025:

(in thousands)	For the Six Months Ended June 30, 2026	2025	Change
Operating expenses:			
Research and development	$ 27,137	$ 6,258	$ 20,879
General and administrative	28,918	6,222	22,696
Acquired in-process research and development	132,957	—	132,957
Total operating expenses	189,012	12,480	176,532
Loss from operations	(189,012)	(12,480)	(176,532)
Total other income	2,769	680	2,089
Net loss	$ (186,243)	$ (11,800)	$ (174,443)

Research and Development Expenses

Research and development expenses were $27.1 million for the six months ended June 30, 2026, compared to $6.3 million for the six months ended June 30, 2025. The increase of $20.9 million was primarily driven by the inclusion of development costs of PIKTOR following the February 2026 acquisition, contributing $6.1 million of research and development costs including preclinical, clinical trial, and CMC related expenses, significant non-recurring costs associated with the Acquisition including $4.8 million of non-cash stock-based compensation expense and $9.1 million of non-recurring tax gross-up payments related to the accelerated vesting of Faeth options, along with $3.3 million of higher personnel costs, including stock-based compensation and incentives, partially offset by a $2.4 million decrease in legacy Sensei programs research and development expenses.

We expect research and development expenses in future periods to be lower than those incurred during the six months ended June 30, 2026, which included significant non-recurring costs associated with the Acquisition, including stock-based compensation expense related to the accelerated vesting of Faeth employee stock options and tax gross-up payments. However, we expect our ongoing research and development expenses to increase significantly as we advance PIKTOR through our ongoing Phase 2 trial in advanced endometrial cancer and our recently initiated Phase 1b/2 trial in HR+/HER2- advanced breast cancer, and as we expand preclinical and CMC activities for our broader pipeline.

General and Administrative Expenses

General and administrative expenses were $28.9 million for the six months ended June 30, 2026, compared to $6.2 million for the six months ended June 30, 2025. The increase of $22.7 million was primarily driven by acquisition-related charges consisting of $6.2 million of non-cash stock-based compensation expense and $6.5 million of non-recurring tax gross-up payments related to the accelerated vesting of Faeth options, $2.5 million of transaction costs, $2.3 million of Faeth operating costs, and $4.5 million of higher personnel costs, including stock-based compensation and incentives, along with a $0.7 million increase primarily due to integration-related professional fees.

We expect our general and administrative expenses in future periods to be lower than those incurred during the six months ended June 30, 2026, which included significant non-recurring costs associated with the Acquisition, including stock-based compensation expense related to the accelerated vesting of Faeth employee stock options and transaction costs. However, we expect our ongoing general and administrative expenses to remain significantly higher than our pre-Acquisition levels as a result of the integration of Faeth Therapeutics' operations, including personnel costs associated with the expanded workforce and the support of our broader product pipeline, as well as additional costs associated with operating as a larger public company, including consulting, legal, tax-related services, accounting, investor relations, and insurance premiums.

Acquired In-Process Research and Development Expense

Acquired in-process research and development expense was $133.0 million for the six months ended June 30, 2026, with no comparable expense in the prior year period. The charge was recognized in connection with the Acquisition in February 2026 and represents the fair value of acquired IPR&D assets that had no alternative future use as of the acquisition date. See Note 3 to our unaudited condensed consolidated financial statement included elsewhere in this Quarterly Report for additional information regarding the acquisition.

Other Income

Other income was $2.8 million for the six months ended June 30, 2026 compared to $0.7 million for the six months ended June 30, 2025. The $2.1 million increase was primarily related to an increase in interest income on securities.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any product revenue and have incurred net losses and negative cash flows from our operations. As of June 30, 2026, we had cash, cash equivalents and marketable securities of $186.4 million. We have financed our operations through sales of our common stock, redeemable convertible preferred stock and convertible debt. Through the date of this Quarterly Report, we have raised an aggregate of $123.4 million of gross proceeds from private placements of our equity and convertible debt securities and net proceeds of $138.5 million from our IPO in February 2021 and an additional $183.1 million in net proceeds received in the 2026 Private Placement. Our net loss was $186.2 million and $11.8 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $469.4 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and general and administrative expenditures.

We expect our cash requirements to increase as we advance PIKTOR through multiple clinical trials following the Acquisition, including our ongoing Phase 2 trial in advanced endometrial cancer and our recently initiated Phase 1b/2 trial in HR+/HER2- advanced breast cancer, and we believe our existing cash, cash equivalents and marketable securities of $186.4 million are sufficient to fund operations through topline data readouts from both studies.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below (in thousands):

	For the Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	$ (26,406)	$ (13,003)
Net cash (used in) provided by investing activities	(139,502)	15,948
Net cash provided by (used in) financing activities	184,143	(382)
Net increase in cash and cash equivalents	$ 18,235	$ 2,563

Operating Activities

During the six months ended June 30, 2026, net cash used in operating activities was $26.4 million, primarily resulting from our $186.2 million net loss partially offset by a $9.8 million increase in our operating assets and liabilities and increases in non-cash charges of $150.0 million, primarily related to $133.0 million of acquired in-process research and development from the Acquisition, $17.4 million of stock compensation expense and $0.7 million of non-cash lease expense partially offset by $1.1 million of accretion on marketable securities. The change in operating assets and liabilities was primarily related to a $10.3 million decrease in prepaid expenses $0.2 million increase in accounts payable and accrued liabilities and a $0.1 million increase in other assets offset by a $0.8 million decrease in operating lease liabilities.

During the six months ended June 30, 2025, net cash used in operating activities was $13.0 million, primarily resulting from our $11.8 million net loss and a $2.3 million decrease in our operating assets and liabilities partially offset by increases in non-cash charges of $1.1 million, primarily related to $0.8 million of non-cash lease expense and $0.7 million of stock compensation expense, partially offset by $0.4 million of accretion on marketable securities.

Investing Activities

During the six months ended June 30, 2026, net cash used in investing activities was $139.5 million, primarily due to $158.6 million in purchases of short-term investments, partially offset by $12.6 million in maturities of short-term investments and $6.5 million in cash assumed from the Acquisition.

During the six months ended June 30, 2025, net cash provided by investing activities was $15.9 million, primarily due to $24.5 million in maturities of short-term investments and $0.2 million of proceeds from the sale of property and equipment, partially offset by $8.8 million in purchases of short-term investments.

Financing Activities

During the six months ended June 30, 2026, net cash provided by financing activities was $184.1 million, primarily consisting of $200.0 million proceeds from the issuance of Series B Preferred Stock, $1.1 million from the exercise of options into common stock, partially offset by $16.9 million of issuance costs from the private placement issuance of Series B Preferred Stock and $0.1 million of principal payments under our financing leases.

During the six months ended June 30, 2025, net cash used in financing activities was $0.4 million, primarily consisting of $0.5 million of principal payments under our financing leases, partially offset by $0.1 million of proceeds from the sale of financing lease assets.

Material Cash Requirements

Our material cash requirements will have an impact on our future liquidity. Our material cash requirements represent material expected or contractually committed future payment obligations.

Operating Leases

We have operating lease arrangements for our corporate offices and lab facilities. As of June 30, 2026, we had operating lease payment obligations of $0.6 million, with $0.5 million payable for the remainder of 2026. See Note 7 in our condensed consolidated financial statements included elsewhere in this Form 10-Q for additional information.

In the biopharmaceutical industry, it can take a significant amount of time and capital resources to successfully complete all stages of research and development and commercialize a product candidate. The ultimate length of time and spend required cannot be accurately estimated as it varies substantially according to the type, complexity, novelty and intended use of a product candidate. Please see the "Funding Requirements" section below for further details.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and potentially seek marketing approval for, our product candidates. In addition, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for our current and future product candidates;
- the cost and timing of the manufacture of additional clinical trial material as well as any costs related to the scale-up of manufacturing activities;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the need to hire additional clinical, quality assurance, quality control and other scientific personnel;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the terms of any collaboration agreements we may choose to enter into, including the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;

- the cost associated with the expansion of our operational, financial and management systems and increased personnel, including personnel to support our operations as a public company; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products, if approved, on our own.

We expect our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through topline data readouts from both our ongoing Phase 2 trial of PIKTOR in advanced endometrial cancer (Study FTH-PIK-201) and our recently initiated Phase 1b/2 trial of PIKTOR in HR+/HER2- advanced breast cancer (Study FTH-PIK-101). We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

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

Critical Accounting Policies and Significant Judgements and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the six months ended June 30, 2026, we acquired in-process research and development intangible assets in connection with the Faeth Therapeutics merger, which represents a new critical accounting policy not previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with

the SEC on March 30, 2026. Except for this addition, there were no other significant changes to our critical accounting policies which are included in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 in our condensed consolidated financial statements included elsewhere in this Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements. Other than as disclosed in our financial statements, we do not expect that any recently issued accounting standards will have a material impact on our financial statements or will otherwise apply to our operations.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an Emerging Growth Company, or EGC, as defined in the JOBS Act. As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

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

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and other procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2026. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2026.

Changes in Internal Control over Financial Reporting

On February 17, 2026, we completed our acquisition of Faeth Therapeutics, as further described in Note 3 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. In connection with the acquisition, we have begun the process of integrating Faeth's financial processes, systems, and personnel into our system of internal control over financial reporting. We expect this integration to continue through the remainder of 2026 and to result in changes to our internal control over financial reporting.

Other than as described above, there were no material changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended June 30, 2026 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report on Form 10-Q. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- We need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to further delay, limit, reduce or terminate our product development or commercialization efforts.
- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the success of our product candidates that we advance into the clinic. All our product candidates will require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially. If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available.
- We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.
- We were not involved in the early development of PIKTOR; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of PIKTOR.
- While emerging clinical data from a competitor has provided evidence supporting the multi-node inhibition concept, there is no guarantee that PIKTOR's specific approach will produce comparable results, and a competitor's first-mover advantage could limit our commercial opportunity.

- We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The success of our product candidates will depend on several factors, including obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for our product candidates.
- If we are unable to obtain and maintain patent protection for our technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.
- There is no guarantee that the Acquisition will increase stockholder value.
- The failure to successfully integrate the businesses of Sensei and Faeth in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Risks Related to Our Financial Position

We have a limited operating history and have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess the future viability of our business prospects. Our operations to date have been limited to business planning, including the Acquisition, organizing and staffing our company, raising capital, identifying potential product candidates, conducting clinical trials and preclinical studies for our development programs, entering into licensing agreements, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations.

We have incurred significant operating losses since our inception and expect to continue to incur losses for the foreseeable future. Our net loss was $186.2 million and $11.8 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $469.4 million and cash, cash equivalents and marketable securities of $186.4 million, which includes $183.1 million in net proceeds received in the 2026 Private Placement. We have funded our operations to date primarily with proceeds from the sale of our equity securities, including the 2026 Private Placement, and historically from borrowings of convertible debt.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of PIKTOR. Investment in clinical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty, particularly with respect to the Acquisition. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, we have used substantial amounts of capital to fund the development of our product candidates and operations. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as our product candidates enter and advance through preclinical studies and clinical trials. We will require substantial additional funding to meet our financial needs and to pursue our business objectives. We will require significant additional capital to, among other things:

- complete our ongoing and planned clinical trials, preclinical studies and IND-enabling activities;
- initiate, enroll, and complete additional clinical trials for our product candidates;
- seek and obtain regulatory approvals for our product candidates;
- build and maintain our manufacturing capabilities or enter into third-party manufacturing arrangements;
- expand and protect our intellectual property portfolio; and
- fund our general and administrative operations.

In addition, if we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

Failure to raise capital as and when needed would have a negative impact on our financial condition and ability to develop our product candidates. Furthermore, we cannot be certain that additional funding will be available on acceptable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives, and any of our current or future license agreements may be terminated if we are unable to meet the payment or other obligations under the agreements.

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

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales are likely to result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment

obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, geopolitical conflicts, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

Fluctuating interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that any clinical trials of our product candidates will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any of our product candidates. All our product candidates are in the early stages of our development efforts, and if any of our product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. While the FDA has not objected to our protocol for PIKTOR in HR+/HER2- breast cancer, there can be no assurance that the FDA will permit any future IND or protocol for our other product candidates or additional indications to go into effect in a timely manner or at all. We would not be permitted to conduct further clinical trials in the United States without future INDs and approved protocols for our other product candidates.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- initiating, enrolling, and completing clinical trials;
- submission of INDs for and receipt of allowance to proceed with our clinical trials or other future clinical trials;
- completing preclinical studies;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully 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;
- manufacturing our product candidates at an acceptable cost; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which could materially harm our business.

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

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain regulatory approval for our preclinical programs. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or our facilities;

- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize our product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, 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.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product candidate or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of our product candidates that we advance into the clinic, particularly PIKTOR. All of our product candidates, including PIKTOR, will require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting substantially all our resources to the development of PIKTOR. Our existing clinical data for PIKTOR is derived from a Phase 1b open-label, uncontrolled study with a limited number of evaluable patients. If PIKTOR encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Because substantially all of our resources are concentrated on a single product candidate, any failure or significant delay in PIKTOR's development would have a disproportionate impact on our business, financial condition and prospects, and we do not have other clinical-stage programs that could offset such a setback.

We cannot provide you with any assurance that we will be able to successfully advance PIKTOR or any additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which could have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

While emerging clinical data from third parties has provided evidence supporting the multi-node inhibition concept for the PI3K/AKT/mTOR pathway, there is no guarantee that PIKTOR's specific approach will produce comparable clinical results, and earlier approvals for third party drugs in this class could limit our commercial opportunity.

Our development strategy for PIKTOR is premised on the hypothesis that simultaneous inhibition of multiple nodes of the PI3K/AKT/mTOR signaling pathway — specifically, concurrent PI3Kα inhibition and mTORC1/2 inhibition — will provide deeper, more durable and more tolerable pathway suppression than currently approved single-node inhibitors. We refer to this approach as multi-node inhibition, or MNI. While recent Phase 3 data for the IV pan-PI3K and mTORC1/2 inhibitor gedatolisib provide clinical evidence supporting the broader MNI concept, there can be no assurance that PIKTOR will produce comparable efficacy or tolerability results in clinical trials.

In July 2026, the FDA approved gedatolisib for the treatment of HR+/HER2-, PIK3CA wild-type metastatic breast cancer, making gedatolisib the first approved MNI therapy for HR+/HER2- advanced breast cancer and enabling it to establish a significant market position before PIKTOR completes clinical development. Accordingly, PIKTOR must demonstrate meaningful differentiation — whether through oral convenience, a favorable tolerability profile, broader patient applicability, or other clinical advantages — in order to compete effectively. There can be no assurance that PIKTOR will be able to demonstrate such differentiation. Furthermore, the PI3K/AKT/mTOR pathway is the subject of intense research, and new modalities or approaches could emerge that are superior to both gedatolisib and PIKTOR, rendering our competitive position obsolete.

In addition, if gedatolisib or another MNI that receives regulatory approval is incorporated into the standard of care for any of our target indications, regulatory authorities may require that future clinical trials of PIKTOR, including any registrational trials, use the newly approved MNI as part of the comparator arm rather than the current standard of care. Such a change could require us to conduct larger, more expensive, and longer clinical trials than currently planned, raise the efficacy threshold that PIKTOR must demonstrate to achieve regulatory approval, and materially increase our development costs and delay our anticipated development timelines. Even if we are able to demonstrate superiority or non-inferiority to a newly approved MNI, the cost, complexity, and duration of the required trials could substantially exceed our current projections, and we may need to raise additional capital to fund such trials. There can be no assurance that we would be able to obtain such additional capital on acceptable terms, or at all.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and effective for use in each target indication, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. A failure of one or more clinical trials can occur at any stage of testing. Any side effects or patient deaths could affect the development of our product candidates, even if deemed to not be drug related.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;

- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdictions to approve our NDAs or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Human clinical trials are expensive, can take many years to complete, and are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for oncology product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

In addition, our ongoing Phase 2 trial in advanced endometrial cancer, Study FTH-PIK-201, includes an optional sub-study in which enrolled patients may combine an insulin-suppressing diet with their PIKTOR plus paclitaxel treatment regimen. Because participation in the diet sub-study is optional, patients who elect to participate may differ in meaningful ways from those who do not, and the resulting patient subgroups may not be balanced with respect to baseline characteristics or other factors that could influence clinical outcomes. If a significant proportion of patients participate in the diet sub-study, or if the diet has any effect — whether positive or negative — on efficacy or tolerability endpoints, it may be difficult to attribute observed clinical outcomes solely to PIKTOR. This could complicate our ability to interpret the trial's results, could raise questions from regulatory authorities, and could reduce the evidentiary value of the trial for purposes of supporting future regulatory submissions or clinical development decisions.

Negative outcomes or data integrity failures by competitors in the oncology space could adversely affect our business, reputation, and the regulatory and commercial environment in which we operate.

The clinical and commercial success of PIKTOR may be influenced not only by our own data and results, but also by the outcomes and perceived integrity of data generated by competitors operating in the same therapeutic area, including other multi-node

inhibitors. If a competitor's product or product candidate is withdrawn from the market, subject to a safety recall, or associated with serious adverse events, whether in clinical trials or following regulatory approval, patients, physicians, payers, and the broader medical community may develop a generalized skepticism or loss of confidence in the underlying treatment modality or target mechanism. This loss of confidence could reduce patient enrollment in our clinical trials, dampen physician adoption of our products, or cause payers to impose more restrictive coverage and reimbursement policies, regardless of whether our products share the specific deficiencies identified in the competitor's product.

We have no control over the research, development, manufacturing, or commercial practices of our competitors in the oncology space, and we cannot predict whether their data or products will meet the standards expected by regulators, the medical community, or the public. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, we are currently focusing the majority of our efforts on the development of PIKTOR. 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 collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. We do not know whether our candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in preclinical or clinical development despite positive results observed in early preclinical studies or having successfully advanced through initial clinical trials. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. Further, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these trials may not be indicative of results of future clinical trials.

We were not involved in the early development of PIKTOR; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of PIKTOR.

We had no involvement with or control over the initial preclinical and clinical development of PIKTOR. We are dependent on third parties having conducted their research and development in accordance with the applicable protocols and legal, regulatory and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such drug product; and having correctly collected and interpreted the data from these trials. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of PIKTOR will be delayed and may be adversely affected.

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

We expect to publish from time to time interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline 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, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

The cross-trial comparisons we present regarding PIKTOR's safety and efficacy profile relative to other PI3K/AKT/mTOR pathway agents are subject to significant limitations and may not be predictive of PIKTOR's relative performance in future controlled studies.

In this Report and in our other public communications, we present data comparing PIKTOR's emerging clinical profile, including rates of hyperglycemia and stomatitis, pharmacokinetic and pharmacodynamic characteristics, and preclinical potency, to published data from clinical trials of approved single-node inhibitors and other multi-node inhibitors in development. These comparisons are derived from different clinical trials conducted at different times, with differences in trial design, patient populations, disease settings, dosing regimens, endpoints, sample sizes, follow-up periods, and adverse event grading criteria. No head-to-head clinical trials have been conducted comparing PIKTOR to any of the agents referenced in these comparisons, and cross-trial comparisons are inherently limited and may not accurately reflect the relative safety or efficacy of the agents being compared.

Physicians, patients, investors, and regulatory authorities may draw conclusions from these cross-trial comparisons that are not supported by the underlying data, or may discount PIKTOR's potential based on the inherent limitations of such comparisons. If PIKTOR's clinical profile does not compare as favorably to competing agents in head-to-head or registrational trials as our cross-trial analyses suggest, the commercial prospects and perceived differentiation of PIKTOR could be materially diminished.

We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial, including with respect to PIKTOR, perceived risks related to results of prior trials of serabelisib and sapanisertib alone or in combination;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- clinicians' and patients' perceptions as to any risks associated with our competitors' product candidates;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and

- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical site available.

In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may 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.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and, therefore, may be small, and our projections regarding the size of the addressable market may be incorrect.

Our approach is based on multi-node inhibition of the PI3K/AKT/mTOR pathway. While emerging Phase 3 data from a competitor have provided clinical evidence supporting this broader concept, our specific product candidate, PIKTOR, has not been evaluated in registrational clinical trials, which makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancers are detected they are treated with first line of therapy with the intention of curing the cancer. This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. If the patient's cancer relapses, then the patient is given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

There is no guarantee that any of our product candidates, even if approved, would be approved for an early line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

Our projections of addressable market opportunity for PIKTOR are based on estimates and assumptions that may prove incorrect, and the actual commercial opportunity may be substantially smaller than we expect.

We have made internal estimates of the total addressable market for PIKTOR and other product candidates targeting the PI3K/AKT/mTOR pathway, including estimates of patient populations, treatment penetration rates, and potential pricing. These estimates are based on a variety of sources, including published scientific literature, epidemiological data, market research and our own assumptions about competitive dynamics. However, these estimates are inherently uncertain and may prove to be materially incorrect.

The actual addressable market for PIKTOR may be smaller than we estimate for several reasons, including: the number of patients with actionable alterations in the PI3K/AKT/mTOR pathway may be lower than projected; physicians may not adopt PIKTOR over established therapies; payors may restrict reimbursement; PIKTOR may initially be approved only for later-line treatment settings with smaller patient populations; competing products may capture significant market share before PIKTOR reaches the market; and advances in precision oncology may further segment the patient population. If the actual market opportunity for PIKTOR is materially smaller than our estimates, we may not be able to generate sufficient revenue to justify our development investment, which could have a material adverse effect on our business and financial condition.

In particular, our estimates of PIKTOR's addressable market include an assumption that multi-node inhibition may confer clinical benefit to patients whose tumors are activated through the PI3K/AKT/mTOR pathway in its non-mutated, or "wild-type," state, either through dysregulated upstream signaling or as an adaptive response to prior therapy. This belief is based on limited clinical data from a small number of patients in an open-label, uncontrolled Phase 1b study in which responses were observed across multiple mutational classifications, including in patients with no detectable pathway mutations, and on our interpretation of PIKTOR's mechanism of action. These observations have not been confirmed in larger or controlled clinical trials and may not be replicated in

our ongoing or planned studies. If multi-node inhibition does not demonstrate meaningful clinical benefit in patients without direct PI3K/AKT/mTOR pathway alterations, the addressable patient population for PIKTOR could be significantly smaller than we currently estimate, which would reduce our anticipated commercial opportunity and could have a material adverse effect on our business, financial condition, and prospects.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials will include cancer patients who are very sick and whose health is deteriorating. It is possible that some of these patients may experience side effects during our clinical trials. For example, in a prior clinical trial of PIKTOR, it was reported that one patient had Grade 3 septic shock that was determined to be drug-related. In addition, PI3K and mTOR inhibitors as a class are associated with known adverse effects including hyperglycemia, stomatitis, diarrhea, rash and hepatotoxicity. These class-effect toxicities have been observed with approved drugs targeting this pathway and may also be associated with PIKTOR. If these or other adverse effects occur with unacceptable frequency or severity in our clinical trials, our ability to develop and commercialize PIKTOR could be materially impaired. Further, patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations, or CROs, or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of

manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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

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

Risks Related to Manufacturing and our Dependence on Third Parties

We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.

We currently rely on third-party CROs, academic institutions, study sites, clinical investigators and others to conduct, supervise, and monitor our preclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we currently have or plan to enter into agreements governing the activities of these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to develop PIKTOR and other current and future product candidates, or we may not obtain marketing approval for, or commercialize, PIKTOR or our other current and future product candidates in a timely manner or at all.

Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities could be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not 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 the development of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by a pandemic limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for current and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize current and future product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for current and future product candidates may be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may enter into collaborations for our current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we plan to conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of current and future product candidates, which could result in additional losses and deprive us of potential product revenue.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

Certain of our current and future product candidates will be evaluated in combination with third-party drugs, and we will have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our ability to develop and ultimately commercialize current and future product candidates used in combination with other compounds will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with the commercialized product, if approved. Any failure to enter into successful commercial relationships, or inability to source or purchase other potential combination agents in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop current and future product candidates as potential combination therapies, which may materially harm our business, financial condition, results of operations, stock price and prospects. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not encountered when developing single-agent product candidates. For example, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. Additionally, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party under terms unfavorable to us to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

We currently rely on CMOs for the production of PIKTOR and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

Because PIKTOR is a combination of two active pharmaceutical ingredients, our manufacturing and supply chain for PIKTOR requires coordination across two separate drug substances, and any disruption to the supply of either component could halt our entire development program. The need to maintain parallel supply chains for two drug substances increases our operational complexity and our vulnerability to supply disruptions compared to single-agent product candidates. We may not be able to secure backup suppliers for both components on commercially reasonable terms. Any significant delay in the supply of either serabelisib or sapanisertib could considerably delay our clinical development, increase our costs, and have a material adverse effect on our business.

We currently have no plans to build our own clinical or commercial scale manufacturing capabilities for our product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for

future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations, or CMOs, as part of our development of our product candidates. These CMOs will provide drug substance intermediate and drug product that will be subsequently labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our product candidates or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce product candidates we may develop in the quantities needed for our clinical trials or, if any current or future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The need to synchronize the procurement of two APIs for our fixed combination drug product candidate PIKTOR presents additional risk since any imbalance in availability and timing of one API would prevent the manufacture of finished drug product for clinical trials or commercial use. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of any current or future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

The facilities used by third-party manufacturers to manufacture current or future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of any of our product candidates. Additionally, any changes implemented by a new CMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current and future product candidates and jeopardize our ability to commence product sales and generate revenue.

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 or commercial 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 or approved by 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 candidates 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 or products. In addition, in the case of CMOs that supply our product candidates, 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.

As part of their manufacture of our product candidates, our CMO and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If our CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of

which could significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of any current or future product candidates for use in clinical trials or for commercial supply;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or second sources of supply with alternative suppliers or CMOs to supplement or supply the raw materials, drug substances, intermediates, and drug product necessary for the manufacture of our product candidates, including PIKTOR. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

Because we rely on a limited number of suppliers for the raw materials used in our drug candidates, any delay, shortage or interruption in the supply of such raw materials or contamination in our manufacturing process could lead to delays in the manufacture and supply of our drug candidates.

We rely on third-parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. For example, we rely on third-parties to supply certain reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Certain of our suppliers or their sub-suppliers are based in China, which exposes us to additional risks including trade restrictions, tariffs, export controls, geopolitical tensions, and potential disruptions to the supply chain that are beyond our control. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our drug candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our drug candidates, could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

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.

Our product candidates and the activities associated with their development and 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. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our clinical trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more controlled clinical trials to obtain approval. Additionally, even if FDA does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. 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 our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies 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 NDA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. 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 disagree with the design or implementation of our preclinical studies or clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- 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 or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical 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;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

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

We may submit marketing applications in countries other than the United States. 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 compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. 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 of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, 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 short, the foreign regulatory approval process involves all of the risks associated with FDA approval. 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 may intend to charge for our products will also be subject to approval.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs

for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may 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. Later discovery of previously unknown problems with a product, 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 the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations 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, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

If we are unable to successfully validate, develop and obtain regulatory approval for any required companion diagnostic tests for our product candidates or experience significant delays in doing so, we may fail to obtain approval or may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may develop or engage third parties to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are subject to regulation by the FDA, EMA and other regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims, including the federal FCA, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by HITECH and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or stock options, could, despite efforts

to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. 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 current or future 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. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, Patient Protection and ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services, or HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be

included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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.

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Compliance with Trade Control laws may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, Trade Control laws prohibit the provision of certain products and services to countries, governments and persons targeted by sanctions.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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 involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination 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. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We currently plan to work to build our commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to expand our sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Additionally, our beliefs that our products will be commercially viable have not been tested.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

We anticipate that we will compete with Alpelisib, Inavolisib, Capivasertib, Everolimus and Temsirolimus, all of which are approved drugs that target the PI3K/AKT/mTOR pathway. In addition, we are aware of several additional product candidates in clinical development that could potentially pose a direct competitive threat to PIKTOR, particularly for the treatment of advanced HR+/HER2- breast cancer. These product candidates include Gedatolisib, an intravenous pan-PI3K + mTORC1/2 inhibitor from Celcuity, whose New Drug Application for HR+/HER2-, PIK3CA wild-type metastatic breast cancer was accepted by the FDA with

Priority Review and a Prescription Drug User Fee Act goal date of July 17, 2026; Tersolisib, an oral mutant-specific PI3Kα inhibitor from Eli Lilly currently in Phase 3 trials for HR+/HER2- breast cancer; Zovegalisib, an oral mutant-selective PI3Kα inhibitor from Relay Therapeutics currently in Phase 3 trials for advanced HR+/HER2- breast cancer; Afuresertib, an oral pan AKT inhibitor from Laekna Therapeutics currently in Phase 3 trials for advanced HR+/HER2- breast cancer; Paxalisib, an oral brain penetrant PI3K/mTOR inhibitor from Kazia Therapeutics currently in Phase 3 trials in glioblastoma; SNV4818, an oral pan-mutant-selective PI3Kα inhibitor acquired by Novartis from Synnovation Therapeutics in March 2026, currently in Phase 1/2 trials for HR+/HER2- breast cancer and other solid tumors; and OKI-219, an oral mutant-specific PI3Kα inhibitor from OnKure Therapeutics, currently in Phase 1/2 trials for HR+/HER2- breast cancer and other solid tumors. In addition, in July 2026, the FDA approved Celcuity's gedatolisib, and in May 2026, Celcuity announced positive topline results from the PIK3CA mutant cohort of its Phase 3 VIKTORIA-1 trial, with both the gedatolisib triplet (gedatolisib plus fulvestrant plus palbociclib) and the gedatolisib doublet (gedatolisib plus fulvestrant) demonstrating statistically significant and clinically meaningful improvements in progression-free survival. Celcuity has indicated that it intends to submit a supplemental New Drug Application to the FDA for the PIK3CA mutant indication, and that detailed data from both VIKTORIA-1 cohorts will be presented at the 2026 American Society of Clinical Oncology Annual Meeting in early June 2026. Gedatolisib establish a meaningful market position before PIKTOR completes clinical development. The two cohorts together cover a substantial portion of the HR+/HER2- advanced breast cancer patient population, which could narrow the addressable population for PIKTOR if gedatolisib achieves favorable approval and reimbursement. Our competitive thesis is that multi-node inhibition is a superior mechanism to provide deeper, more tolerable suppression of the PI3K/AKT/mTOR pathway than is currently available in approved therapeutics. If our thesis is incorrect, or if new modalities are developed that better suppress the PI3K/AKT/mTOR pathway, our business would be materially and adversely impacted.

Several of these competing product candidates are in Phase 3 registrational trials with potential approval timelines that are ahead of our development timeline for PIKTOR. In particular, Celcuity has now reported positive topline Phase 3 results from both the PIK3CA wild-type cohort and the PIK3CA mutant cohort of its VIKTORIA-1 trial, had its New Drug Application for gedatolisib in HR+/HER2-, PIK3CA wild-type metastatic breast cancer approved by the FDA in July 2026, and has announced its intention to file a supplemental New Drug Application for the PIK3CA mutant indication. If one or more competitors obtains regulatory approval and establishes a market position before we are able to enter the market, it could significantly diminish the commercial opportunity for PIKTOR, particularly if the approved product addresses the same patient population or demonstrates a superior safety or efficacy profile. Additionally, mutant-selective PI3Ka inhibitors being developed by Eli Lilly (tersolisib) and Relay Therapeutics (zovegalisib) are also in Phase 3 development and, if approved, could reduce the addressable market for PIKTOR by providing an alternative targeted approach for patients with PI3K-mutant tumors. Large pharmaceutical companies are making significant investments in the PI3K/AKT/mTOR space. For example, in March 2026, Novartis announced the acquisition of Synnovation Therapeutics' pan-mutant-selective PI3Kα inhibitor program, including SNV4818, which is currently in Phase 1/2 clinical development for HR+/HER2- breast cancer. This and similar acquisitions could result in additional well-resourced competitors with established commercial infrastructure entering the market ahead of or concurrent with PIKTOR, which could significantly diminish our commercial opportunity.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either their product or a specific indication before we are able to enter the market.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially

successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- 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;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement 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 and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance could harm our business and could require us to seek additional financing.

Even if our product candidates, if approved, 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 adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our

products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which could negatively impact prescriptions for our product candidates, if approved.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years and biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

In addition, our NEAAR program, which seeks to restrict patient intake of specific non-essential amino acids to suppress tumor growth, represents a novel therapeutic approach for which there is limited regulatory precedent. Dietary interventions are not subject to the same well-established regulatory approval pathways as pharmaceutical products, and it is unclear how the FDA or comparable foreign regulatory authorities would evaluate a dietary regimen as a component of a cancer treatment regimen. Even if we are able to generate clinical evidence supporting the use of NEAAR in combination with our other product candidates, third-party payors may be unwilling to provide coverage or reimbursement for a prescribed dietary intervention, which could limit patient adoption and reduce any potential commercial value of the program.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Our business, operational and financial goals may not be attainable if the market opportunities for our products are smaller than we expect. Our internal research and third-party estimates may not accurately reflect the market opportunities for PIKTOR or our other product candidates today or in the future.

The total market opportunities that we believe exist are based on a variety of assumptions and estimates, including the size of the addressable patient population in applicable jurisdictions, the penetration of other drugs in these markets, the number of potential companion diagnostic programs we will be able to successfully pursue, the amount of potential milestone payments that we could receive in companion diagnostic programs, the number of patients we will test in clinical trials, the price we will be able to charge for our products and the total annual number of cancer patients with undiagnosed abnormal cell signaling. In addition, we have relied on third-party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of cancer patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the objective response rates of drug therapies, the number of deaths caused by cancer and the expected growth in cancer drug therapy and diagnostic markets. Our internal research and estimates on market opportunities have been verified by independent sources, but any or all of our assumptions and/or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our products or such patients becoming difficult to identify and access, limited reimbursement for our products, pricing pressure due to availability of alternative drugs or an inability to obtain the necessary regulatory approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we may not attain our business, operational and financial goals.

Inadequate funding for the FDA, the SEC and other government agencies 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.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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.

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets

We rely upon a combination of patents, trade secret protection, trademarks, and confidentiality agreements to protect the intellectual property related to our product candidates and development programs. Our success depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. 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. 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. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our present and future 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 prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent position of biopharmaceutical companies are generally uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States

or in other countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application.

Moreover, we have in the past, and may in the future be subject to a third-party pre-issuance submission of prior art to the USPTO. We may also become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidate(s) for an indication that is outside of the methods of use claimed in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their products for indications that are covered by our patents, clinicians may prescribe these competitor products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that patent searches, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

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

The United States has enacted and implemented wide-ranging patent reform legislation. 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 actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms.

Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidate(s), or the use of our product candidate(s). As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidate(s) or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidate(s).

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Furthermore, as the patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may face commercial competition, which could harm our business. We cannot provide any assurances that third-party patents do not exist which might be

enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may develop or license intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to future licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies may provide funding, facilities, personnel, or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may retain rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products. For example, research resulting in future in-licensed patent rights and technology that was funded in part by the U.S. government could result in the government having certain rights, or march-in rights, to such patent rights and technology which may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology, potentially on unfavorable terms or without adequate compensation.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Because of a lower evidentiary standard in these USPTO post-grant 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention or that the other party's use of our patented technology falls under the

safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

We employ individuals and retain independent contractors and consultants who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, independent contractors, consultants, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such persons' former companies or other third parties. We may also be subject to claims that such persons or other third parties have an ownership interest in our intellectual property. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and 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, valuable intellectual property. 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.

In addition, while we require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

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

We are party to certain license agreements (e.g. with Takeda and The Regents) pursuant to which we were granted rights to intellectual property in connection with the development, manufacture and commercialization of certain product candidates. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, and in the event of termination we may not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our research and licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and our collaborators;
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

In addition, our license agreements do, and we expect that future license agreements will, impose various diligence, milestone payment, royalty, insurance and/or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology, and could compromise our development and commercialization efforts for our product candidates.

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

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional

resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. 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, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, defending and enforcing patents and trademarks on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent or trademark applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being

approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. In addition, many countries limit the enforceability of patents against government agencies or government contractors. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidate(s). While we will endeavor to try to protect our technologies and product candidate(s) with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and unpredictable.

In addition, geopolitical actions in the United States and in other countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents or those of any future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. We rely on our outside counsel or third-party vendors to pay these fees. The USPTO, CIPO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our present and future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to our Business Operations

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

As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need and to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if our product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial and human resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, as the competition for individuals in oncology product development is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and the expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. Our senior management may terminate their employment with us at any time, and we do not maintain “key person” insurance for any of our employees.

The Acquisition resulted in a combined management team that is small relative to our development ambitions. We are heavily dependent on a limited number of individuals with specialized expertise in PI3K/AKT/mTOR pathway biology, metabolic oncology, and clinical development of combination products. The loss of one or more of these individuals, particularly during the critical

post-Acquisition integration period, could significantly delay our clinical development programs. Competition for individuals with this specialized expertise is intense, and we may not be able to recruit suitable replacements on acceptable terms or in a timely manner.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Following the Acquisition, certain of our employees who previously worked at a private company are now subject to public company compliance obligations, and any failure to comply with these obligations could expose us to regulatory risk and reputational harm.

As a result of the Acquisition, a number of individuals who previously operated in a private company environment are now employees or officers of a publicly traded company and are subject to public company compliance obligations, including compliance with our insider trading policy, Section 16 reporting requirements under the Securities Exchange Act of 1934, Regulation FD restrictions on selective disclosure of material nonpublic information, and quiet period restrictions around SEC filings. These individuals may not have prior experience with public company compliance requirements.

We have implemented onboarding and training programs to educate former Faeth employees regarding these obligations. However, there can be no assurance that all individuals will fully understand or consistently comply with these requirements, particularly during the initial post-Acquisition integration period. Any inadvertent violation of insider trading laws, Section 16 reporting obligations, or Regulation FD could result in SEC enforcement action, personal liability for the individuals involved, and reputational harm to the company. Such violations could also undermine investor confidence in our corporate governance practices and adversely affect the trading price of our common stock.

If we engage in future acquisitions or strategic collaborations, 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 may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- 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 partnership, 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 regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We do not currently maintain product liability insurance because we have determined that the cost of available coverage is not justified relative to our current stage of clinical development. Once we are ready for a product launch, we intend to bind a policy with product liability insurance coverage in the aggregate and a per incident limit at an amount adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we re-initiate our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to our Securities and our Status as a Public Company

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

The trading price of our common stock 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. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates ;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;
- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;

- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common stock or other securities or other reasons may in the future cause us to become the target of securities litigation or stockholder activism.

Securities litigation and stockholder activism, including proxy contests, could result in substantial costs and divert management's and the Board of Director's attention and resources from our business. The potential of a proxy contest or other stockholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements registering the issuance of all shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Furthermore, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Finally, in connection with the execution of the Agreement and Plan of Merger, or the Merger Agreement, dated as of February 17, 2026, by and among the Company, Sapphire First Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company, Sapphire Second Merger Sub, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, Faeth Subsidiary and Faeth HoldCo, certain of our directors and officers, as well as certain of the directors, officers and stockholders of Faeth Therapeutics, each as of immediately prior to the Acquisition, entered into lock-up agreements, pursuant to which each such stockholder is subject to a 180-day lockup on the sale or transfer of shares of our common stock and Series B Preferred Stock held by each such stockholder, including those shares received by directors and officers in the Acquisition, subject to certain limited

exceptions as set forth in such lock-up agreements. Upon expiration of this 180-day lockup period, these shares will become eligible for sale in the public market. Pursuant to the Merger Agreement and the registration rights agreement that we entered into pursuant to the 2026 Private Placement, filed a resale registration statement with the SEC to register the resale of shares of our common stock underlying the Series B Preferred Stock and warrant to purchase shares of Series B Preferred Stock, and such shares shares subject to the registration statement now no longer constitute restricted securities and may be sold freely in the public markets, subject to any beneficial ownership limitations set by the holder of Series B Preferred Stock. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, compliance with any new requirements adopted by the PCAOB, disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and the requirements of holding advisory "say-on-pay" votes on executive compensation and stockholder advisory votes on golden parachute compensation not previously approved. Certain of these reduced reporting requirements and exemptions are also available to us due to the fact that we qualify as a "smaller reporting company" under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting, are not required to provide a compensation discussion and analysis, are not required to provide a pay-for-performance graph or CEO pay ratio disclosure and may present only two years of audited financial statements and related MD&A disclosure.

Under the JOBS Act, we will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities; and (4) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Under current SEC rules, however, we will continue to qualify as a "smaller reporting company" for so long as (i) we have a public float (i.e., the market value of common equity held by non-affiliates) of less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million.

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

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

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in

our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Changes in tax law could adversely affect our business and financial condition.

We are subject to federal, state and local income and other taxes in the United States and in foreign jurisdictions because of the scope of our operations. New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the U.S. government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act that (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other taxing authorities with respect to this and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business. To the extent that any such changes in tax laws and regulations have a negative impact on us, including as a result of related uncertainty, our business, financial condition, results of operations and cash flows may be materially and adversely impacted and we may be required to implement changes to minimize increases in our tax liability.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2025, we had NOL carryforwards for federal and state income tax purposes of approximately $170.5 million and $98.9 million, respectively, a portion of which expired beginning in 2025. Net operating loss carryforwards generated after December 31, 2017 for federal tax reporting purposes of $137.2 million have an indefinite life. The remaining federal net operating losses are subject to a 20-year carryforward period.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Following the approval of the Company Stockholder Matters on June 10, 2026, the Acquisition resulted in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use. Faeth's NOL carryforwards may also be subject to limitations as a result of prior shifts in equity ownership and/or the Acquisition. We may also have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of Faeth that we acquired as a result of the Acquisition may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have incurred and expect to continue incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, as a private company. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability

insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. Depending upon our filer status, we could also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as required by Section 404(b). To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, or DGCL, our certificate of incorporation or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws;
- any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, or the Exchange Act, or any claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation will provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If any other court of competent jurisdiction were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Insiders have substantial influence over us and could cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or in the best interest of our stockholders.

We believe that our directors, executive officers and principal stockholders, together with their affiliates, own, in the aggregate, a substantial portion of our outstanding common stock. As a result, if these or certain of these stockholders were to choose to act together, they may be able to affect the outcome of matters submitted to our stockholders for approval, as well as our management and affairs, such as:

- the composition of our board of directors;

- the adoption of amendments to our certificate of incorporation and bylaws;
- the approval of mergers or sales of substantially all of our assets;
- our capital structure and financing; and
- the approval of contracts between us and these stockholders or their affiliates, which could involve conflicts of interest.

This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company and making some transactions more difficult or impossible without the support of these stockholders, even if such transactions are beneficial to other stockholders;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- requiring us to engage in transactions that may not be agreeable to or in the best interest of us or other stockholders.

Risks Related to the Acquisition

There is no guarantee that the Acquisition will increase stockholder value.

In February 2026, we consummated the Acquisition, pursuant to which we acquired Faeth, and we closed the 2026 Private Placement. We cannot guarantee that implementing the Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Acquisition poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Acquisition to our stockholders.

The failure to successfully integrate the businesses of the Company and Faeth Therapeutics in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Our ability to successfully integrate the operations of the Company and Faeth Therapeutics will depend, in part, on our ability to realize the anticipated benefits from the Acquisition. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Acquisition may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the integration of the Company's and Faeth's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. There can be no assurance that we will effectively manage the increased complexity of our business without experiencing operating inefficiencies or control deficiencies. Delays encountered in the integration process could have a material adverse effect on our expenses, operating results and financial condition, including the value of shares of our common stock.

We expect to incur substantial expenses related to the integration of Faeth.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Acquisition and the integration of Faeth. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including accounting and finance, billing, payroll, and benefits. Both the Company and Faeth have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement, and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Acquisition, and the amount and timing of such charges are uncertain at present.

General Risk Factors

Our business, operations and clinical development plans and timelines, as well as the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers, equipment suppliers and others, could be adversely affected by the effects of health epidemics.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. The effects of government orders may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

If our information systems or data, or those of our collaborators, contractors, consultants or other third parties with whom we work, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or, collectively, process, proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets and clinical trial data, or, collectively, sensitive information.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, attacks enhanced or facilitated by artificial intelligence, or AI, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

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

Future or past business transactions (such as acquisitions or mergers) expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication

technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Remote work has increased risks to our information systems and data, as personnel utilize network connections, computers and devices outside of our premises or network.

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

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures.

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

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, this could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. 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 data. Such an actual or perceived security incident could also cause us to experience other adverse consequences, such as: loss of, or damage to, our data or applications, inappropriate disclosure of confidential or proprietary information, legal liability, exposure to litigation (including class claims) and regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, harm to our competitive position, reputational damage, and delay in the further development and commercialization of our product candidates.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration

demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous privacy and data security laws, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, many states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services if we become subject to these laws. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act ("CCPA") applies to personal data of consumers, business representatives, and employees who are California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other U.S. state comprehensive consumer privacy laws exempt certain personal data processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work should we become subject to these laws. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels, and we expect more governments to pass similar laws in the future. The evolving patchwork of local, state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") the United Kingdom's General Data Protection Regulation ("UK GDPR") (collectively, "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and India's Information Technology Act and supplementary rules, impose strict requirements for processing personal data. The EU GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European Economic Area ("EEA") residents. Among other things, the EU GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data over prior EU law and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The EU GDPR also provides for substantial fines for breaches and violations (up to the greater of €20 million or 4% of annual global revenue). The EU GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR.

We increasingly use artificial intelligence and machine learning tools across our operations and business functions, and we expect our use of such tools to expand over time. While we believe that the responsible use of AI tools can enhance our operational efficiency, these tools present risks that could adversely affect our business. AI-generated outputs may be inaccurate, incomplete, or misleading, and reliance on such outputs without adequate human oversight could result in errors in regulatory submissions, clinical or scientific analyses, contractual provisions, or public disclosures. In addition, the input of proprietary, confidential, or sensitive information into third-party AI platforms could result in the inadvertent disclosure of trade secrets, attorney-client privileged materials, or material nonpublic information. The regulatory landscape governing the use of AI in the life sciences and pharmaceutical industries is rapidly evolving, and new laws, regulations, or guidance — including those arising from the current administration's policy initiatives — could impose additional compliance obligations, restrict certain uses of AI tools, or increase our exposure to regulatory enforcement actions or litigation. Any failure to adequately govern our use of AI tools could result in reputational harm, regulatory scrutiny, or legal liability. In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or

rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are considered "foreign persons" and majority owned by, organized under the laws of, primarily resident in, or a contractor of a covered person or country of concern, as applicable) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In addition to data privacy and security laws, we are and may in the future become bound by contractual obligations and industry standards related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy obligations) are quickly changing, becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change aspects of our business model or our clinical trials.

Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

Our operations, and those of our vendors and suppliers, could be subject to power shortages, telecommunications failures, water shortages, civil unrest, labor disputes, violence, earthquakes, floods, hurricanes, typhoons, fires, extreme weather conditions, infectious disease, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates on a patient-by-patient basis. 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.

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

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

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

(a) Recent Sales of Unregistered Equity Securities

None.

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

Not applicable.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended June 30, 2026, none of our officers or directors, as defined in Rule 16a-1(f), adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits, Financial Statement Schedules.

(3) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 11, 2021).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on June 13, 2025).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on December 9, 2022).
3.4	Certificate of Designations of the Series A Junior Participating Cumulative Preferred Stock of the Registrant, dated March 7, 2023 (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 8-A, filed with the Securities and Exchange Commission on March 7, 2023, File No. 005-92222)

3.5	Certificate of Elimination of the Series A Junior Participating Cumulative Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Annual Report on Form 10-K (File No. 001-39980), filed with the SEC on March 28, 2025).
3.6	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026).
10.1#	Sensei Biotherapeutics, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39980), filed with the SEC on May 15, 2026).
10.2#	Sensei Biotherapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39980), filed with the SEC on May 15, 2026).
10.3*#	Employment Agreement, dated March 11, 2026, by and between the Registrant and Brian Stephenson.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

# Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Faeth Therapeutics, Inc.

Date: August 4, 2026 By: /s/ Anand Parikh
Anand Parikh
Principal Executive Officer

Date: August 4, 2026 By: /s/ Brian Stephenson
Brian Stephenson
Principal Financial Officer

Date: August 4, 2026 By: /s/ Josiah Craver
Josiah Craver
Senior Vice President of Finance
Principal Accounting Officer

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "***Agreement***") is entered into effective as of March 11, 2026 (the "***Effective Date***"), by and between Sensei Biotherapeutics, Inc. (the "***Company***") and Brian Stephenson, PhD (the "***Executive***").

The Company desires to employ Executive in the capacity of full-time Head of Operations and Finance pursuant to the terms of this Agreement and, in connection therewith, to compensate Executive for Executive's personal services to the Company; and

Executive wishes to be employed by the Company and provide personal services to the Company in return for certain compensation.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. EMPLOYMENT BY THE COMPANY.

1.1. At-Will Employment. Executive shall be employed by the Company on an "at-will" basis, meaning either the Company or Executive may terminate Executive's employment at any time, with or without cause or advanced notice. Any contrary representations that may have been made to Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between Executive and the Company on the "at-will" nature of Executive's employment with the Company, which may be changed only in an express written agreement signed by Executive and a duly authorized officer of the Company.

1.2. Position. Subject to the terms set forth herein, the Company agrees to employ Executive in the position of Head of Operations and Finance, and Executive hereby accepts such employment. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company.

1.3. Duties. Executive will report to the Company's President (*"President")* performing such duties as are normally associated with Executive's then-current position and such duties as are assigned to Executive from time to time, subject to the oversight and direction of the President. In addition, Executive will work with the President and other members of the Company's executive management team on strategic planning, business direction and performance, and corporate priorities and action plans. Executive shall perform Executive's duties under this Agreement remotely. In addition, Executive shall make such business trips to such places as may be necessary or advisable for the efficient operations of the Company, including but not limited to board meetings and corporate offsite meetings.

1.4. Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Executive will be eligible to participate on the same basis as similarly situated employees in the Company's benefit plans in effect from time to time during Executive's employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COMPENSATION.

2.1. Salary. Executive shall receive for Executive's services to be rendered hereunder an initial annualized base salary of $525,000, subject to review and adjustment from time to time by the Company in its sole discretion ("***Base Salary***"). The Base Salary is payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices.

2.2. Annual Bonus. Executive shall be eligible to receive an annual performance bonus of up to 40% (the "***Target Percentage***") of Executive's then-current Base Salary ("***Annual Bonus***"). The Annual Bonus will be based upon the Company's assessment of Executive's performance, the Company's attainment of targeted goals as set by the Company's Board of Directors (the "***Board***") in its sole discretion,

overall economic conditions and forecasts, and related financial factors, all as determined by the Company in its sole discretion. The Annual Bonus, if any, will be subject to applicable payroll deductions and withholdings. Following the close of 2026 and each calendar year thereafter, the Company will determine whether Executive has earned the Annual Bonus, and the amount of any Annual Bonus (which can be less than the Target Percentage), based on the set criteria. No amount of the Annual Bonus is guaranteed, and Executive must be an employee in good standing on the Annual Bonus payment date to be eligible to receive an Annual Bonus. No partial or prorated bonuses will be provided; *provided, however,* that solely for the 2026 performance year Executive will be eligible for a prorated bonus based on Executive's start date. Executive's eligibility for an Annual Bonus is subject to change in the discretion of the Board (or any authorized committee thereof).

2.3. Initial Option Grant. Subject to approval by the Board (or a duly authorized committee thereof), Executive shall be granted an option to purchase up to 166,435 shares of common stock of the Company as a material inducement to Executive's entering into employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4) (the "***Initial Option***"). The Initial Option shall be granted outside of the Company's 2021 Equity Incentive Plan (the "***2021 Plan***") but shall be subject to terms and conditions substantially similar to those set forth in the 2021 Plan, except as otherwise provided in this Agreement or in the stock option agreement evidencing the Initial Option (the "Option Agreement"). The Initial Option shall be granted at a per share exercise price equal to the fair market value (determined in accordance with the 2021 Plan) of the Company's common stock on the date of grant (the "***Initial Option Grant Date***"), and shall be a nonstatutory stock option not intended to qualify as an "incentive stock option" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "***Code***"). Twenty-five percent (25%) of the shares subject to the Initial Option shall vest upon the first (1st) anniversary of the Initial Option Grant Date, and the remaining seventy-five percent (75%) of the shares subject to the Initial Option shall vest in equal monthly installments on the last day of each calendar month for a three (3) year period thereafter, such that all of the shares subject to the Initial Option shall be fully vested on the fourth (4th) anniversary of the Initial Option Grant Date, provided that Executive remains employed by the Company on each vesting date, except as otherwise set forth herein or in the Option Agreement.

2.4. Expense Reimbursement. The Company will reimburse Executive for all reasonable, documented business expenses incurred in connection with Executive's services hereunder, in accordance with the Company's business expense reimbursement policies and procedures as may be in effect from time to time. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A (as defined below): (i) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (ii) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (iii) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

3. CONFIDENTIAL INFORMATION, INVENTION ASSIGNMENT, NON-SOLICITATION, AND NON-COMPETITION OBLIGATIONS. As a condition of employment and in consideration of the benefits that Executive is eligible to receive under this Agreement, including, but not limited to, the compensation offered and provided to Executive hereunder, and as an express condition of the offer and provision of such additional compensation to Executive, Executive agrees to execute and abide by the Company's Confidential Information, Invention Assignment, Non-Solicitation and Non-Competition Agreement (the "***Covenants Agreement***") attached hereto as **Exhibit A**. The Covenants Agreement may be amended by the parties from time to time without regard to this Agreement. The Covenants Agreement contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement.

4. OUTSIDE ACTIVITIES. Except with the prior written consent of the Board, Executive will not, while employed by the Company, undertake or engage in any other employment, consulting engagement, occupation or business enterprise that would, in the Company's discretion, interfere with Executive's responsibilities and the performance of Executive's duties hereunder. Subject to the foregoing, Executive may engage in the following activities: (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve; (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; (iii) Executive's participation in professional and academic activities; (iv) service on the board of directors of one (1) for-profit company at a time, provided that (A) Executive has received prior written approval from the Board for such service, which approval may be granted or withheld in the Board's sole discretion, (B) such company is not a competitor of the Company and does not present a conflict of interest with Executive's obligations to the Company, (C) such service does not interfere with Executive's duties and responsibilities to the Company, and (D) the Board may revoke its approval at any time upon written notice to Executive if the Board determines, in its sole discretion, that such service has become inconsistent with the

Company's interests or Executive's obligations hereunder; and (v) such other activities as may be specifically approved by the Board. This restriction shall not, however, preclude Executive from managing personal investments or owning less than one percent (1%) of the total outstanding shares of a publicly-traded company.

5. NO CONFLICT WITH EXISTING OBLIGATIONS. Executive represents that Executive's performance of all the terms of this Agreement and as an employee of the Company do not and will not breach any agreement or obligation of any kind made prior to Executive's employment by the Company, including agreements or obligations Executive may have with prior employers or entities for which Executive has provided services. Executive has not entered into, and Executive agrees that Executive will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. TERMINATION OF EMPLOYMENT. The parties acknowledge that Executive's employment relationship with the Company will be at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without "Cause" (as defined in Section 6.3(a) below). The provisions in this Section 6 govern the amount of compensation, if any, to be provided to Executive upon termination of employment and do not alter this at-will status. Upon any termination of employment, the Executive will be entitled to receive the Accrued Obligations (defined below). Executive will be paid all of the Accrued Obligations at such time as required by law. For purposes of this Agreement, "***Accrued Obligations***" are: (i) Executive's accrued but unpaid salary through the date of termination, and (ii) any unreimbursed business expenses incurred by Executive payable in accordance with the Company's standard expense reimbursement policies.

6.1. Termination by the Company Without Cause or Resignation by Executive for Good Reason (not in Connection with a Change in Control).

6.1.1.1.The Company shall have the right to terminate Executive's employment with the Company pursuant to this Section 6.1 at any time without Cause by giving notice as described in Section 6.7 of this Agreement. A termination pursuant to Section 6.5 or 6.6 below is not a termination without Cause for purposes of receiving the Non-CIC Severance Benefits described in this Section 6.1 or the CIC Severance Benefits described in Section 6.2 below.

6.1.1.2.If the Company terminates Executive's employment at any time without Cause or Executive resigns his employment with the Company for "Good Reason" (as defined in Section 6.1(g) below), in either case, at any time outside of the Change in Control Measurement Period (both "Change in Control" and "Change in Control Measurement Period" as defined in Section 6.2 below), then, provided such termination also constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), and Executive complies with the obligations in Section 6.1(c) below, Executive shall also be eligible to receive the following "***Non-CIC Severance Benefits***:"

6.1.1.2.1.The Company will pay Executive an amount equal to Executive's then current Base Salary for nine (9) months, less all applicable withholdings and deductions, paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in Section 6.1(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter; and

6.1.1.2.2.Provided Executive or Executive's covered dependents, as the case may be, timely elects continued coverage under COBRA, or state continuation coverage (as applicable), under the Company's group health plans following such termination, the Company will pay the portion of the COBRA, or state continuation coverage, premiums which is equal to the cost of the coverage that the Company was paying as of the date of termination, to continue Executive's (and Executive's covered dependents, as applicable) health insurance coverage in effect on the termination date until the earliest of: (1) nine (9) months following the termination date; (2) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (3) the date Executive ceases to be eligible for COBRA or state law continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (1)-(3), (the "***Non-CIC COBRA Payment Period***")). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA, or state continuation coverage, premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying such premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the Non-CIC COBRA Payment Period, a fully

taxable cash payment equal to the COBRA or state continuation coverage premium for such month, subject to applicable tax withholding, for the remainder of the Non-CIC COBRA Payment Period. Nothing in this Agreement shall deprive Executive of Executive's rights under COBRA or ERISA for benefits under plans and policies arising under Executive's employment by the Company.

6.1.1.3.Executive shall only be eligible to receive the Non-CIC Severance Benefits pursuant to Section 6.1(b) or the CIC Severance Benefits pursuant to Section 6.2(a) of this Agreement if: (i) by the sixtieth (60th) day following the date of Executive's Separation from Service, Executive has signed and delivered to the Company a separation agreement containing an effective, general release of claims in favor of the Company and its affiliates and representatives, in the form presented by the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if Executive holds any other positions with the Company or any affiliate, including a position on the Board, Executive resigns such position(s) to be effective no later than the date of Executive's termination date (or such other date as requested by the Board); (iii) Executive returns all Company property; (iv) Executive complies with all post-termination obligations under this Agreement and the Covenants Agreement; and (v) Executive complies with the terms of the Release, including without limitation any non-disparagement and confidentiality provisions contained in the Release.

6.1.1.4.The Non-CIC Severance Benefits provided to Executive pursuant to this Section 6.1 are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Company severance plan, policy, program, or prior agreement with the Company. For avoidance of doubt, Executive shall not be eligible for both CIC Severance Benefits and Non-CIC Severance Benefits.

6.1.1.5.For purposes of this Agreement, "***Good Reason***" shall mean the occurrence of any of the following events without Executive's consent: (i) a material reduction in Executive's Base Salary of at least 10%, other than pursuant to a reduction proportionately affecting all of the Company's other senior level executive employees; (ii) a material reduction in Executive's duties, authority and/or responsibilities relative to Executive's duties, authority, and/or responsibilities in effect immediately prior to such reduction; (iii) the Executive no longer reports to the CEO or the Board; (iv) the relocation of Executive's principal place of employment, without Executive's consent, in a manner that lengthens Executive's one-way commute distance by fifty (50) or more miles from Executive's then-current principal place of employment immediately prior to such relocation; or (v) any material breach of this Agreement by the Company; *provided, however,* that, any such termination by Executive shall only be deemed for Good Reason pursuant to this definition if: (1) Executive gives the Company written notice of Executive's intent to terminate for Good Reason within thirty (30) days following the first occurrence of the condition(s) that Executive believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the ***"Company Cure Period***"); (3) the Company has not, prior to receiving such notice from Executive, already informed Executive that Executive's employment with the Company is being terminated; and (4) Executive voluntarily terminates Executive's employment within thirty (30) days following the end of the Company Cure Period.

6.2. Termination by the Company without Cause or Resignation by Executive for Good Reason (in connection with a Change in Control).

6.2.1.1.In the event that Executive's employment is terminated without Cause or Executive resigns his employment for Good Reason within twelve (12) months following the effective date of a Change in Control ("***Change in Control Measurement Period***") of the Company, then, provided such termination also constitutes a ***Separation from Service***, and Executive complies with the obligations in Section 6.1(c) above, including but not limited to the Release requirement and Executive's continued compliance with obligations to the Company under Executive's Covenants Agreement, then Executive will be eligible for the following "***CIC Severance Benefits***":

6.2.1.1.1.The Company or its successor will pay Executive an amount equal to Executive's then current Base Salary for twelve (12) months, less all applicable withholdings and deductions, paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date, with the remaining installments occurring on the Company's or its succesor's regularly scheduled payroll dates thereafter;

6.2.1.1.2.Provided Executive or Executive's covered dependents, as the case may be, timely elects continued coverage under COBRA, or state continuation coverage (as applicable), under the Company's or its successor's group health plans following such termination, the Company or its

successor will pay the portion of the COBRA, or state continuation coverage, premiums which is equal to the cost of the coverage that the Company or its successor was paying as of the date of termination, to continue Executive's (and Executive's covered dependents, as applicable) health insurance coverage in effect on the termination date until the earliest of: (1) twelve (12) months following the termination date; (2) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (3) the date Executive ceases to be eligible for COBRA or state law continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (1)-(3), (the "***CIC COBRA Payment Period***")). Notwithstanding the foregoing, if at any time the Company or its successor determines that its payment of COBRA, or state continuation coverage, premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying such premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the CIC COBRA Payment Period, a fully taxable cash payment equal to the COBRA or state continuation coverage premium for such month, subject to applicable tax withholding, for the remainder of the CIC COBRA Payment Period. Nothing in this Agreement shall deprive Executive of Executive's rights under COBRA or ERISA for benefits under plans and policies arising under Executive's employment by the Company;

6.2.1.1.3.The Company or its successor will make a lump sum cash payment to Executive in an amount equal to one (1) times the Target Percentage for the year in which the termination occurs, subject to standard deductions and withholdings, which will be paid in a lump sum on the same day as the first installment of the severance payment contemplated by Section 6.2(a)(i); and

6.2.1.1.4.Effective as of Executive's termination date, the vesting and exercisability of all outstanding equity awards held by Executive immediately prior to the termination date (if any) shall be accelerated in full. For the avoidance of doubt, vesting acceleration under this subsection is conditioned upon the actual consummation of a Change in Control.

6.2.1.2.For purposes of this Agreement, a "***Change in Control***" shall have the meaning set forth in the 2021 Plan, as amended from time to time.

6.2.1.3.The CIC Severance Benefits provided to Executive pursuant to this Section 6.2 are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Company or successor severance plan, policy or program.

6.3. Termination by the Company for Cause.

Subject to Section 6.3(b) below, the Company shall have the right to terminate Executive's employment with the Company at any time for Cause by giving notice as described in Section 6.7 of this Agreement.

6.3.1.1."***Cause***" for termination shall mean that the Company has determined in its sole discretion that Executive has engaged in any of the following: (i) a material breach of any covenant or condition under this Agreement or any other agreement between the parties; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) any material violation of any Company policy or any act of misconduct; (v) the refusal to follow or implement a clear and reasonable directive of the Company; (vi) negligence or incompetence in the performance of Executive's duties; or (vii) breach of fiduciary duty; *provided, however,* that, any such termination by Company shall only be deemed for Cause pursuant to this definition if: (1) Company gives the Executive written notice of Company's intent to terminate for Cause within thirty (30) days following the Company first having knowledge of the condition(s) that Company believes constitute(s) Cause, which notice shall describe such condition(s); (2) With respect to the conduct described in subsections (i), (iv), (v), and (vi) only, Executive fails to remedy such curable condition(s) within thirty (30) days following receipt of the written notice (the ***"Executive Cure Period***"); and (3) Company terminates Executive's employment within thirty (30) days following the end of the Executive Cure Period.

6.3.1.2.In the event Executive's employment is terminated at any time for Cause, Executive will not receive the Non-CIC Severance Benefits, the CIC Severance Benefits, or any other severance compensation or benefit, except that, consistent with the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

6.4. Resignation by Executive (other than for Good Reason).

6.4.1.1.Executive may resign for any reason from Executive's employment with the Company at any time by giving notice as described in Section 6.7.

6.4.1.2.In the event Executive resigns from Executive's employment with the Company (other than for Good Reason), Executive will not receive the Non-CIC Severance Benefits, the CIC Severance Benefits, or any other severance compensation or benefit, except that, consistent with the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

6.5. Termination by Virtue of Death or Disability of Executive.

6.5.1.1.In the event of Executive's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll policies, provide to Executive's legal representatives Executive's Accrued Obligations, but neither Executive nor Executive's legal representatives will be eligible for the Non-CIC Severance Benefits, the CIC Severance Benefits, or any other severance compensation or benefit.

6.5.1.2.Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to the Executive, to terminate this Agreement based on Executive's Disability (as defined below). Termination by the Company of Executive's employment based on "***Disability***" shall mean termination because Executive is unable due to a physical or mental condition to perform the essential functions of Executive's position with or without reasonable accommodation for six (6) months in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Executive's employment is terminated based on Executive's Disability, Executive will not receive the Non-CIC Severance Benefits, the CIC Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations and any disability insurance and/or other group benefits to which Executive may be entitled as a result of his Disability.

6.6. Termination Due to Discontinuance of Business. Anything in this Agreement to the contrary notwithstanding, in the event the Company's business is discontinued because rendered impracticable by substantial financial losses, lack of funding, legal decisions, administrative rulings, declaration of war, dissolution, national or local economic depression or crisis or any reasons beyond the control of the Company, then this Agreement shall terminate as of the day the Company determines to cease operation with the same force and effect as if such day of the month were originally set as the termination date hereof. In the event this Agreement is terminated pursuant to this Section 6.6, Executive will not receive the Non-CIC Severance Benefits, the CIC Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

6.7. Notice; Effective Date of Termination.

6.7.1.1.Termination of Executive's employment pursuant to this Agreement shall be effective on the earliest of:

6.7.1.1.1.immediately after the Company gives notice to Executive of Executive's termination, with or without Cause, unless pursuant to Section 6.3(a)(vi) in which case ten (10) days after notice if not cured, or unless the Company specifies a later date, in which case, termination shall be effective as of such later date;

6.7.1.1.2.immediately upon Executive's death;

6.7.1.1.3.immediately after the Company gives written notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later Separation Date, in which case, termination shall be effective as of such later Separation Date, *provided* that Executive has not returned to the full-time performance of Executive's duties prior to such date;

6.7.1.1.4.except as addressed by Section 6.7(a)(v), forty-five (45) days (or such shorter period agreed to by the President and Executive in writing) after Executive gives written notice to the Company of Executive's resignation for any reason, *provided* that the Company may set a

Separation Date at any time between the date of notice and the date of resignation, in which case Executive's resignation shall be effective as of such other date. Executive will receive compensation through any required notice period; or

6.7.1.1.5.for a resignation for Good Reason, immediately upon Executive's full satisfaction of the requirements of Section 6.1(e).

6.7.1.2.The actual date the Executive's employment is terminated or resigned shall be the "***Separation Date.***" In the event notice of a termination under subsection Section 6.7 (a)(i) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five (5) business days of the request in compliance with the requirement of Section 7.1 below. In the event of a termination for Cause or a resignation for Good Reason, written confirmation shall specify the subsection(s) of the definition of Cause or the definition of Good Reason relied on to support the decision to terminate.

6.8. Cooperation With Company After Termination of Employment. Following termination of Executive's employment for any reason, Executive shall reasonably cooperate with the Company in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company.

6.9. Effect of Termination. Executive agrees that should Executive's employment be terminated for any reason, Executive shall be deemed to have resigned from any and all positions with the Company and its subsidiaries.

6.10. Application of Section 409A.

6.10.1.1.It is intended that all of the compensation payable under this Agreement, to the greatest extent possible, either complies with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") and the regulations and other guidance thereunder and any state law of similar effect (collectively, "***Section 409A***") or satisfies one or more of the exemptions from the application of Section 409A, and this Agreement will be construed in a manner consistent with such intention, incorporating by reference all required definitions and payment terms.

6.10.1.2.No severance payments will be made under this Agreement unless Executive's termination of employment constitutes a Separation from Service. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

6.10.1.3.To the extent that any severance payments are deferred compensation under Section 409A, and are not otherwise exempt from the application of Section 409A, then, to the extent required to comply with Section 409A, if the period during which Executive may consider and sign the Release spans two calendar years, the severance payments will not begin until the second calendar year. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Executive is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Executive's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the severance will be delayed as follows: on the earlier to occur of (a) the date that is six months and one day after Executive's Separation from Service, and (b) the date of Executive's death, the Company will: (i) pay to Executive a lump sum amount equal to the sum of the severance benefits that Executive would otherwise have received if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.10(c); and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Sections 6.1 and 6.2. No interest shall be due on any amounts deferred pursuant to this Section 6.10(c).

6.10.1.4.To the extent required to avoid accelerated taxation and/or tax penalties under Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not affect amounts reimbursable or provided in any subsequent year.

6.10.1.5.Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non- compliance with Section 409A.

6.11. Excise Tax Adjustment.

6.11.1.1.If any payment or benefit Executive will or may receive from the Company or otherwise (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment provided pursuant to this Agreement (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax, or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state, and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***").

6.11.1.2.Notwithstanding any provision of this Section 6.11 to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

6.11.1.3.Unless Executive and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity, or group effecting the Change in Control transaction, the Company shall appoint a nationally-recognized accounting or law firm to make the determinations required by this Section 6.11. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

6.11.1.4.If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 6.11(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 6.11(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 6.11(a), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

7. GENERAL PROVISIONS.

7.1. Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after

deposit with a nationally-recognized overnight courier, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll or Executive's Company-provided email address, or at such other address as the Company or Executive may designate by ten (10) days' advance written notice to the other.

7.2. **Severability**. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3. **Waiver**. If either party should waive any breach of any provisions of this Agreement, such party shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.4. **Complete Agreement**. This Agreement, and the Covenants Agreements, constitute the entire agreement between Executive and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Executive and an authorized officer of the Company. The parties have entered into or are entering into a separate Covenants Agreement in connection herewith and have or may enter into separate agreements related to equity awards. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Executive's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

7.5. **Counterparts**. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same agreement.

7.6. **Headings**. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.7. **Successors and Assigns**. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. Executive may not assign or transfer this Agreement or any rights or obligations hereunder, other than to Executive's estate upon Executive's death.

7.8. **Choice of Law**. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the State of California.

7.9. **Resolution of Disputes**. To aid the rapid and economical resolution of disputes that may arise in connection with Executive's employment with the Company, and in exchange for the mutual promises contained in this Agreement, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment, shall be resolved to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("***JAMS***") or its successor, under JAMS' then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: (i) https://www.jamsadr.com/rules-employment-arbitration/ and (ii) https://www.jamsadr.com/rules-comprehensive-arbitration/) at a location closest to where Executive last worked for the Company or another mutually agreeable location. Any demand for arbitration must be made within the statute of limitations applicable to the claim asserted as if such claim were asserted in court. Failure to demand arbitration (or, where applicable, file a counterclaim, crossclaim, or third-party claim) within such time limitation shall serve as a waiver and release with respect to all such claims. **Executive acknowledges that by agreeing to this arbitration procedure, both Executive andthe Company waive the**

right to resolve any such dispute through a trial by jury or judge. The Federal Arbitration Act, 9 U.S.C. § 1 et seq., will, to the fullest extent permitted by law, govern the interpretation and enforcement of this arbitration agreement and any arbitration proceedings. This provision shall not be mandatory for any claim or cause of action to the extent applicable law prohibits subjecting such claim or cause of action to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"), such as non-individual claims that cannot be waived under applicable law, claims or causes of action alleging sexual harassment or a nonconsensual sexual act or sexual contact, or unemployment or workers' compensation claims brought before the applicable state governmental agency. In the event Executive or the Company intends to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Executive acknowledges and agrees that proceedings of any non-individual claim(s) under the California Private Attorneys General Act ("PAGA") that may be brought in court shall be stayed for the duration and pending a final resolution of the arbitration of any individual or individual PAGA claim. Nothing herein prevents Executive from filing and pursuing proceedings before a federal or state governmental agency, although if Executive chooses to pursue a claim following the exhaustion of any applicable administrative remedies, that claim would be subject to this provision. In addition, with the exception of Excluded Claims arising out of 9 U.S.C. § 401 et seq., all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class, representative, or collective proceeding, nor joined or consolidated with the claims of any other person or entity. Executive acknowledges that by agreeing to this arbitration procedure, both Executive and the Company waive all rights to have any dispute be brought, heard, administered, resolved, or arbitrated on a class, representative, or collective action basis. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. If a court finds, by means of a final decision, not subject to any further appeal or recourse, that the preceding sentences regarding class, representative, or collective claims or proceedings violate applicable law or are otherwise unenforceable, as to a particular claim or request for relief, the parties agree that any such claim(s) or request(s) for relief be severed from the arbitration and may proceed in a court of law rather than by arbitration. All other claims or requests for relief shall be arbitrated. Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration and procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator to decide, provided however, that if required by applicable law, a court and not the arbitrator may determine the enforceability of this paragraph with respect to Excluded Claims. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as Executive or the Company would otherwise be entitled to seek in a court of law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall pay all JAMS arbitration administrative fees in excess of the administrative fees that Executive would be required to pay if the dispute were filed in a court of law. Each party is responsible for its own attorneys' fees, except that the arbitrator may award reasonable attorneys' fees and costs to the prevailing party in the arbitration when authorized by any written agreement between Executive and Company or as otherwise authorized under applicable law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

[SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties have executed this Employment Agreement on the day and year first written above.

SENSEI BIOTHERAPEUTICS, INC.

By: /s/ Christopher W. Gerry
Name: Christopher W. Gerry
Title: President and General Counsel

EXECUTIVE:

By: /s/ Brian Stephenson, PhD
Name: Brian Stephenson, PhD

Exhibit 31.1

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

I, Anand Parikh, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 of Faeth Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: August 4, 2026

By: /s/ Anand Parikh
Anand Parikh
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Brian Stephenson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 of Faeth Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: August 4, 2026

By: /s/ Brian Stephenson
Brian Stephenson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Anand Parikh, President and Chief Executive Officer of Faeth Therapeutics, Inc. (the "Company"), and Brian Stephenson, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of the 4th day of August 2026.

/s/ Anand Parikh
Anand Parikh
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Brian Stephenson
Brian Stephenson
Chief Financial Officer
(Principal Financial Officer)

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