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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 September 30, 2026

or

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

For the transition period from _____ to

Commission File Number: 001-40675

Immuneering Corporation

(Exact name of registrant as specified in its charter)

Delaware	26-1976972
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
245 Main St. **Second Floor** **Cambridge, MA**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 500-8080
(Registrant's telephone number, including area code)

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

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Class A common stock, par value $0.001 per share	**IMRX**	**The Nasdaq Global Market**

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

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

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

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

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

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

As of October 23, 2026 the registrant had 64,763,155 shares of Class A common stock, $0.001 par value per share, issued and outstanding and 0 shares of Class B common stock, $0.001 par value per share, issued and outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements including within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including without limitation statements regarding our plans to develop, manufacture and commercialize our product candidates (including whether as potential monotherapies or in combination with other therapeutic agents), the design, timing, disclosure of data, or outcome of our ongoing or planned preclinical studies or clinical trials involving atebimetinib (also referred to as IMM-1-104), any of our other pipeline product candidates and any future product candidates, the clinical utility of our product candidates when administered alone or in combination with other therapeutic agents, the filing with, and approval by, regulatory authorities of our product candidates, the sufficiency of funds to operate the business of the Company and related expected cash runway, and our plans regarding raising additional capital, are forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, those described in the sections of this Quarterly Report on Form 10-Q entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These risks and uncertainties include, but are not limited to:

- our limited operating history;
- our history of operating losses;
- our ability to raise the substantial additional capital that will be required to finance our operations;
- the difficulty of obtaining regulatory approval for any of our current or future product candidates;
- our limited experience in designing and conducting clinical trials;
- the timing of the initiation, progress and potential results of our ongoing and planned clinical trials and our research programs, including our ongoing Phase 1/2a clinical trial of atebimetinib and MAPKeeper 301 registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- our ability to successfully complete our clinical trials, including our ongoing Phase 1/2a clinical trial of atebimetinib and MAPKeeper 301 registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- the risk of substantial delays in completing, if at all, the development and commercialization of our current or future product candidates;
- risks related to adverse events, toxicities or other undesirable side effects caused by our current or future product candidates;
- the risk of delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, including in our MAPKeeper 301 registrational trial of atebimetinib in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer;
- our ability to submit an Investigational New Drug application ("IND"), or IND amendments or comparable documents in foreign jurisdictions in order to commence clinical trials on the timelines we expect;

- our substantial reliance on the successful development of our current and future product candidates, as well as our platform, including our proprietary technologies;
- risks related to competition in our industry;
- the market opportunity for our product candidates, if approved;
- risks related to manufacturing;
- risks related to our reliance on third parties;
- risks related to our intellectual property;
- risks related to ongoing and future pandemics, or other widespread adverse health events; and
- other important risk factors that could affect the outcome of the events set forth in these statements and that could affect our operating results and financial condition described in Part II, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless otherwise stated or the context requires otherwise, references to “Immuneering,” the “Company,” “we,” “us,” and “our,” refer to Immuneering Corporation and its subsidiaries.

Risk Factors Summary

We are subject to numerous risks and uncertainties, including those further described below in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following are principal factors that may offset our competitive strengths or have a negative effect on our business strategy, which could materially adversely affect our business, financial conditions, results of operations, future growth prospects, or cause a decline in the price of our common stock:

- We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products, have not completed any registrational clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable with respect to outcomes. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.
- We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The outcome of preclinical studies and earlier clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.
- Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications that we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.
- Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our platform and capabilities to build a pipeline of product candidates with commercial value.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

- We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations ("CROs"), to conduct certain aspects of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We contract with third parties, including contract manufacturing organizations ("CMOs") and consultants, for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or be able to acquire such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

- If we are unable to obtain and maintain patent and/or other intellectual property protection for our product candidates and technologies, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize our product candidates, products (if any) and technology may be impaired, and we may not be able to compete effectively in our market.

- Acquisitions, joint ventures or other transactions involving third parties could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 58,226,805	$ 128,645,025
Marketable securities	87,178,645	44,186,244
Prepaids and other current assets	5,305,154	3,414,685
Total current assets	150,710,604	176,245,954
Marketable securities, non-current	20,712,253	44,183,186
Property and equipment, net	808,952	938,481
Goodwill	6,690,431	6,690,431
Intangible asset, net	299,197	321,147
Right-of-use assets	3,039,783	3,322,249
Other assets	299,827	283,562
Total assets	$ 182,561,047	$ 231,985,010
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,758,219	$ 1,542,737
Accrued expenses	7,498,137	7,842,367
Other liabilities	89,419	291,513
Lease liabilities	445,496	397,104
Total current liabilities	10,791,271	10,073,721
Long-term liabilities:		
Lease liabilities, net of current portion	3,089,079	3,427,321
Total liabilities	13,880,350	13,501,042
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; 0 shares issued or outstanding at September 30, 2026 and December 31, 2025	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2026 and December 31, 2025; 64,763,155 and 64,648,230 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	64,763	64,648
Class B common stock, $0.001 par value, 20,000,000 shares authorized at September 30, 2026 and December 31, 2025; 0 shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Additional paid-in capital	504,409,076	498,658,072
Accumulated other comprehensive income (loss)	(549,153)	81,332
Accumulated deficit	(335,243,989)	(280,320,084)
Total stockholders' equity	168,680,697	218,483,968
Total liabilities and stockholders' equity	$ 182,561,047	$ 231,985,010

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

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 20,721,243	$ 10,867,983	$ 45,363,112	$ 32,793,835
General and administrative	5,059,459	4,505,406	14,738,398	12,807,465
Amortization of intangible asset	7,317	7,317	21,950	21,950
Total operating expenses	25,788,019	15,380,706	60,123,460	45,623,250
Loss from operations	(25,788,019)	(15,380,706)	(60,123,460)	(45,623,250)
Other income (expense)				
Interest income	1,204,598	415,831	3,647,786	1,178,362
Other income, net	390,838	—	1,551,769	—
Net loss	**$ (24,192,583)**	**$ (14,964,875)**	**$ (54,923,905)**	**$ (44,444,888)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.38)	$ (0.85)	$ (1.20)
Weighted-average common shares outstanding, basic and diluted	64,714,194	39,670,095	64,690,275	37,077,041
Other comprehensive loss:				
Unrealized loss from marketable securities	(142,913)	—	(630,485)	—
Comprehensive Loss	**$ (24,335,496)**	**$ (14,964,875)**	**$ (55,554,390)**	**$ (44,444,888)**

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

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value				
Balance at December 31, 2025	64,648,230	$ 64,648	—	$ —	$ 498,658,072	$ 81,332	$ (280,320,084)	$ 218,483,968
Issuance of common stock upon exercise of stock options	4,696	5	—	—	10,430	—	—	10,435
Issuance of common stock through employee stock purchase plan	35,989	36	—	—	170,289	—	—	170,325
Stock-based compensation expense	—	—	—	—	1,636,675	—	—	1,636,675
Net loss	—	—	—	—	—	—	(13,460,895)	(13,460,895)
Other comprehensive loss	—	—	—	—	—	(322,337)	—	(322,337)
Balance at March 31, 2026	64,688,915	$ 64,689	—	$ —	$ 500,475,466	$ (241,005)	$ (293,780,979)	$ 206,518,171
Issuance of common stock upon exercise of stock options	8,487	8	—	—	24,600	—	—	24,608
Stock-based compensation expense	—	—	—	—	1,627,909	—	—	1,627,909
Net loss	—	—	—	—	—	—	(17,270,427)	(17,270,427)
Other comprehensive loss	—	—	—	—	—	(165,235)	—	(165,235)
Balance at June 30, 2026	64,697,402	$ 64,697	—	$ —	$ 502,127,975	$ (406,240)	$ (311,051,406)	$ 190,735,026
Issuance of common stock upon exercise of stock options	26,766	27	—	—	73,010	—	—	73,037
Issuance of common stock through employee stock purchase plan	38,987	39	—	—	147,098	—	—	147,137
Stock-based compensation expense	—	—	—	—	2,060,993	—	—	2,060,993
Net loss	—	—	—	—	—	—	(24,192,583)	(24,192,583)
Other comprehensive loss	—	—	—	—	—	(142,913)	—	(142,913)
Balance at September 30, 2026	64,763,155	$ 64,763	—	$ —	$ 504,409,076	$ (549,153)	$ (335,243,989)	$ 168,680,697

	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value				
Balance at December 31, 2024	31,050,448	$ 31,050	—	$ —	$ 265,650,362	$ —	$ (224,295,186)	$ 41,386,226
Issuance of common stock under at-the-market offering, net of issuance costs	4,836,804	4,837	—	—	13,671,830	—	—	13,676,667
Issuance of common stock through employee stock purchase plan	98,450	98	—	—	133,794	—	—	133,892
Stock-based compensation expense	—	—	—	—	1,692,267	—	—	1,692,267
Net loss	—	—	—	—	—	—	(15,046,132)	(15,046,132)
Balance at March 31, 2025	35,985,702	$ 35,985	—	$ —	$ 281,148,253	$ —	$ (239,341,318)	$ 41,842,920
Issuance of common stock upon exercise of stock options	1,604	2	—	—	2,053	—	—	2,055
Stock-based compensation expense	—	—	—	—	1,524,943	—	—	1,524,943
Net loss	—	—	—	—	—	—	(14,433,881)	(14,433,881)
Balance at June 30, 2025	35,987,306	$ 35,987	—	$ —	$ 282,675,249	$ —	$ (253,775,199)	$ 28,936,037
Issuance of common stock upon exercise of stock options	47,221	47	—	—	136,598	—	—	136,645
Issuance of common stock through employee stock purchase plan	201,693	202	—	—	287,816	—	—	288,018
Issuance of common stock under at-the-market offering, net of issuance costs	327,355	327	—	—	1,343,052	—	—	1,343,379
Issuance of common stock, pre-funded warrants, and common stock warrants through private placement, net of $1.6 million offering costs	5,251,349	5,251	—	—	23,388,922	—	—	23,394,173
Issuance of common stock through public offering, net of commissions, underwriting discounts and $0.4 million in offering costs	18,959,914	18,960	—	—	164,068,015	—	—	164,086,975
Issuance of common stock through private placement with Aventis Inc., net of $0.1 million in offering costs.	2,708,559	2,709	—	—	23,297,291	—	—	23,300,000
Stock-based compensation expense	—	—	—	—	1,456,080	—	—	1,456,080
Net loss	—	—	—	—	—	—	(14,964,875)	(14,964,875)
Balance at September 30, 2025	63,483,397	$ 63,483	—	$ —	$ 496,653,023	$ —	$ (268,740,074)	$ 227,976,432

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

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2026 and 2025
(Unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (54,923,905)	$ (44,444,888)
Adjustments to reconcile to net loss to net cash used in operating activities:		
Depreciation and amortization expense	251,983	248,628
Reduction in carrying amount of right-of-use assets	282,466	255,660
Intangible asset amortization	21,950	21,950
Stock-based compensation expense	5,325,576	4,673,290
Net accretion of discount on marketable securities	(1,343,376)	—
Change in assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(1,697,830)	1,904,097
Other assets	(16,265)	802,848
Increase (decrease) in:		
Accounts payable	1,215,482	(474,214)
Accrued expenses	(344,229)	1,908,736
Lease liabilities	(289,849)	(246,528)
Other liabilities	(202,094)	(153,576)
Net cash used in operating activities	(51,720,091)	(35,503,997)
Cash flows from investing activities:		
Purchases of property and equipment	(122,455)	(18,316)
Purchases of marketable securities	(84,176,216)	—
Maturities of marketable securities	65,175,000	—
Net cash used in investing activities	(19,123,671)	(18,316)
Cash flows from financing activities:		
Proceeds from exercise of stock options	108,080	138,700
Proceeds from issuance of common stock under employee stock purchase plan	317,462	421,910
Proceeds from issuance of common stock under at-the-market offering, net of issuance costs	—	15,020,046
Proceeds from sale of common stock, prefunded warrants and common stock warrants through private placement	—	24,998,919
Proceeds from public offering of common stock, net of commissions and underwriting	—	164,500,006
Proceeds from issuance of common stock through private placement with Aventis Inc	—	25,000,000
Payment of offering and placement costs	—	(3,138,911)
Net cash provided by financing activities	425,542	226,940,670
Net increase (decrease) in cash and cash equivalents	(70,418,220)	191,418,357
Cash and cash equivalents at beginning of period	128,645,025	36,144,720
Cash and cash equivalents at end of period	$ 58,226,805	$ 227,563,077
Supplemental disclosures of noncash information:		
Offering and placement costs included in accounts payable/accrued expenses	$ —	$ 845,933

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

IMMUNEERING CORPORATION
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1 – Organization and Nature of Business

Immuneering Corporation, a Delaware corporation (“Immuneering” or the “Company”), was incorporated in 2008. Immuneering is a late-stage clinical oncology company seeking to develop medicines for broad populations of cancer patients, with an initial aim to therapeutically address patients harboring RAS and/or RAF mutations. The Company aims to achieve broad activity through Deep Cyclic Inhibition® ("DCI") of the mitogen-activated protein kinase ("MAPK") pathway, impacting cancer cells while sparing healthy cells. Immuneering’s lead product candidate, atebimetinib (also referred to as IMM-1-104), is currently in a Phase 1/2a clinical trial in patients with advanced solid tumors harboring RAS or RAF mutations and in a Phase 3 registrational trial (known as "MAPKeeper 301") in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer patients. The Company is developing atebimetinib as a once-daily oral therapy, aiming for activity through DCI of the MAPK pathway at the level of mitogen-activated protein kinase kinase ("MEK"). The Company’s development pipeline also includes early-stage programs.

On October 30, 2019, Immuneering formed a wholly owned subsidiary, Immuneering Securities Corporation (“ISC”), a Massachusetts securities corporation, for the sole purpose of buying, selling and holding securities on the Company’s behalf.

On December 22, 2021, the Company acquired all outstanding shares of capital stock of BioArkive, Inc. (“BioArkive”), a California corporation, which as a result became a wholly owned subsidiary.

Immuneering, ISC and BioArkive are collectively referred to as the “Company” throughout these interim condensed consolidated financial statements.

The Company is subject to a number of inherent risks associated with any biotechnology company that has substantial expenditures for research and development. These risks include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing drug product and conducting clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. There can be no assurance that the Company’s research and development programs will be successful. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees, advisors, and consultants.

On August 10, 2022, the Company entered into an Equity Distribution Agreement (the "2022 Sales Agreement") with Piper Sandler & Co (the "Sales Agent"), to sell shares of its common stock with aggregate gross proceeds of up to $50 million, from time to time, through an “at the market” equity offering program (the "2022 ATM Program"). The Company did not sell any shares of common stock under the 2022 ATM Program during the three and nine months ended September 30, 2026. The Company sold 327,355 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $4.27, for aggregate gross proceeds of $1.4 million ($1.3 million net of offering expenses) during the three months ended September 30, 2025. The Company sold 5,164,159 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the nine months ended September 30, 2025.

On April 20, 2023, the Company completed an underwritten follow-on equity offering, pursuant to which it issued and sold 2,727,273 shares of its Class A common stock $0.001 par value per share at an offering price of $11.00 per share. The aggregate net proceeds received by the Company from the offering were $28,200,003, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company of $203,768.

On August 13, 2025, the Company entered into an Equity Distribution Agreement (the "2025 Sales Agreement") with the Sales Agent, to sell shares of its common stock with aggregate gross proceeds of up to $100 million, from time to time, through an “at the market” equity offering program (the "2025 ATM Program"). In connection with the September 2025 Offering (as defined below), the Company: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by $1,250,007 (the "Reduced Amount"), resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. The Company did not sell any shares of common stock under the 2025 ATM Program during the three and nine months ended September 30, 2026 or September 30, 2025, respectively.

On August 21, 2025, the Company entered into a Securities Purchase Agreement (the "August 2025 Purchase Agreement") with the purchasers party thereto, pursuant to which the Company agreed to sell securities to such purchasers in a private placement (the “August 2025 Private Placement”). The August 2025 Purchase Agreement provided for the sale and issuance by the Company to the purchasers of: (i) an aggregate of 5,251,349 shares of its common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to the same number of shares of its common stock, and (iii) an aggregate of 2,848,096 warrants (the “Purchase Warrants”) to purchase up to the same number of shares of its common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant). On October 6, 2025, certain purchasers from the August 2025 Private Placement exercised an aggregate of 1,077,764 Pre-Funded Warrants previously issued to them pursuant to the August 2025 Purchase Agreement. Each such exercise was made pursuant to the cashless exercise provision of the applicable Pre-Funded Warrant, such that an aggregate of 166 shares of common stock were withheld in lieu of cash payment of the $0.001 exercise price for each Pre-Funded Warrant share, and the exercising purchasers were issued an aggregate of 1,077,598 shares of common stock (the "October 2025 Cashless Exercise"). Following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of September 30, 2026, no Purchase Warrants had been exercised. As of September 30, 2026, the Company had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

On September 24, 2025, the Company entered into a Securities Purchase Agreement (the "September 2025 Purchase Agreement") with Aventis Inc. ("Aventis"), a wholly owned subsidiary of Sanofi, a French société anonyme ("Sanofi"), pursuant to which the Company agreed to sell securities to Aventis in a private placement (the “September 2025 Private Placement”). The September 2025 Purchase Agreement provided for the sale and issuance by the Company to Aventis of an aggregate of 2,708,559 shares of its common stock at a purchase price of $9.23 per share. The Company received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

On September 26, 2025, the Company completed an underwritten follow-on equity offering, pursuant to which it issued and sold 18,959,914 shares of its Class A common stock at an offering price of $9.23 per share (the "September 2025 Offering"), with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by the Company from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

To date, the Company has primarily funded its operations with proceeds from the sale of its capital stock, warrants to purchase stock, and convertible notes. The Company has incurred recurring losses over the past several years and as of September 30, 2026, the Company had an accumulated deficit of $335.2 million. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations. Management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern, and concluded that there are none as it estimates that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these unaudited condensed consolidated financial statements.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The interim condensed consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (“FASB”). The FASB sets generally accepted accounting principles (“GAAP”) to ensure the interim condensed consolidated financial statements are consistently reported. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification ("ASC"). The interim condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

There have been no material changes to the accounting policies of the Company as those set forth in Note 2 to the audited consolidated financial statements contained in the Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Unaudited Interim Financial Information

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with GAAP and in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with GAAP have been omitted from the unaudited interim condensed consolidated financial statements, as is permitted by such rules and regulations. While we believe that the disclosures presented are adequate in order to make the information not misleading, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes for the year ended December 31, 2025.

It is management’s opinion that these financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company’s financial position, operating results and cash flows. Net loss for any interim period is not necessarily indicative of future or annual results.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses during the reporting periods. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities and the recording of expenses that are not readily apparent from other sources. Significant estimates reflected in these interim condensed consolidated financial statements include but are not limited to: the accrued research and development expenses, the determination of fair value of stock-based awards, and the impairment of goodwill and intangible assets. Actual results may differ materially and adversely from these estimates.

Goodwill

Goodwill represents the excess of the fair value of the acquiree over the recognized basis of the net identifiable assets acquired and includes the future economic benefits from other assets that could not be individually identified and separately recognized. Goodwill is not amortized, but instead is periodically reviewed for impairment and an impairment charge is recorded in the periods in which the recorded carrying value of goodwill exceeds its fair value.

On a quarterly basis, the Company performs a review of its business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, the Company would perform an impairment test of goodwill as of the end of the quarter and record any noted impairment loss. The Company performs its annual impairment test during the fourth quarter of each fiscal year.

There were no impairments identified for the year ended December 31, 2025 or for the three and nine months ended September 30, 2026.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other third-party charges related to ongoing equity financings as deferred offering costs until fully consummated. These costs are to be recorded as a reduction of the offering's proceeds which are recorded to additional paid-in capital within stockholders' equity. Should the Company choose not to initiate such financing, the deferred offering costs would be immediately expensed as operating expenses.

Deferred offering costs associated with the 2025 Sales Agreement are reclassified to additional paid-in capital on a pro-rata basis when the Company completes offerings under the 2025 Sales Agreement. Any remaining deferred costs will be expensed to the statement of operations should the planned offering be abandoned. The Company had approximately $0.2 million of deferred offering costs as of September 30, 2026 and $0.2 million as of December 31, 2025.

Common Stock Warrants

The Company accounts for warrants issued as a separable unit in connection with sale of common stock as either liability or equity in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480-10") or ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ("ASC 815-40"). Under ASC 480-10, warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. If warrants do not require liability classification under ASC 815-40 or other applicable generally accepted accounting principles in the United States of America ("U.S. GAAP") the warrants should be classified as equity.

The proceeds received from the sale of equity classified warrants and shares of common stock in a bundled transaction are allocated based on the relative fair values of warrants and shares with no changes in fair value of warrants recognized after the issuance date.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration for potentially dilutive securities. The pre-funded warrants are included as outstanding shares in the computation as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Recently Issued But Not Yet Adopted Accounting Pronouncements and Legislation

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period and, as a result, the Company will not be required to adopt certain new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In November 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU 2024-03"). The guidance in ASU 2024-03 aims to improve disclosures around an entity's expenses. Upon adoption, companies will be required to disclose in the notes to the financial statements a disaggregation of certain expense categories included within the expense captions on the face of the income statement. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods in fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this standard's potential impact on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued Update ASU 2025-11, "Interim Reporting (Topic 270): Narrow-Scope Improvements". This ASU clarifies and improves existing interim reporting guidance by consolidating disclosure requirements within Topic 270 and introducing a disclosure principle requiring entities to disclose events and changes occurring after the most recent annual reporting period that are expected to have a material effect on the entity's financial condition or results of operations. The ASU does not introduce significant changes to recognition or measurement guidance. The amendments in this Update are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effect of adopting this pronouncement on its financial statements and disclosures.

Note 3 – Marketable Securities

Marketable securities consisted of the following as of September 30, 2026 and December 31, 2025, respectively.

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Current:				
U.S. Treasuries	$ 64,528,277	$ —	$ (248,707)	$ 64,279,570
Debt securities	6,434,040	—	(14,507)	6,419,533
Commercial paper	16,498,744	—	(19,202)	16,479,542
Total current	87,461,061	—	(282,416)	87,178,645
Non-current:				
U.S. Treasuries	13,468,760	—	(166,402)	13,302,358
Government securities	7,510,256	—	(100,361)	7,409,895
Total non-current	20,979,016	—	(266,763)	20,712,253
Total marketable securities	$ 108,440,077	$ —	$ (549,179)	$ 107,890,898

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Current:				
U.S. Treasuries	$ 6,495,181	$ 5,504	$ —	$ 6,500,685
Government securities	7,943,758	4,742	—	7,948,500
Debt securities	7,628,117	496	(59)	7,628,554
Commercial paper	22,102,080	6,425	—	22,108,505
Total current	44,169,136	17,167	(59)	44,186,244
Non-current:				
U.S. Treasuries	37,717,598	58,682	—	37,776,280
Government securities	3,998,584	—	(1,544)	3,997,040
Debt securities	2,406,640	3,226	—	2,409,866
Total non-current	44,122,822	61,908	(1,544)	44,183,186
Total marketable securities	$ 88,291,958	$ 79,075	$ (1,603)	$ 88,369,430

The Company's marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities and are recorded at fair value. Unrealized gains (losses) are included as a component of accumulated other comprehensive loss in the condensed consolidated balance sheets and statements of stockholders' equity and a component of total comprehensive loss in the condensed consolidated statements of comprehensive loss, until realized. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis.

The Company's marketable securities portfolio contains investments in U.S. Treasury, other U.S. government-backed securities, and commercial paper. The Company reviews its portfolio based on the underlying risk profile of the securities and does not expect there to be a loss on these investments. The Company also regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions.

There were no impairments recorded during the three and nine months ended September 30, 2026 or September 30, 2025. Realized gains and losses are included in other income (expense) on the condensed consolidated statements of operations.

During the three and nine months ended September 30, 2026 and 2025, the Company recognized no year-to-date credit loss related to its short-term investments, and had no allowance for credit loss recorded as of September 30, 2026 or December 31, 2025.

Note 4 – Fair Value Measurements

The Company records cash equivalents and marketable securities at fair value. ASC 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently, at the end of each reporting period, valued utilizing third-party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market-based approaches, and observable market inputs to determine value. After completing its valuation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2026 and December 31, 2025.

The following table summarizes the Company's cash equivalents measured at fair value on a recurring basis as of September 30, 2026:

	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market	$ 55,476,703	$ —	$ —	$ 55,476,703
Commercial paper	—	2,494,800	—	2,494,800
Total cash equivalents	$ 55,476,703	$ 2,494,800	$ —	$ 57,971,503
Marketable securities:				
U.S. Treasuries	$ 77,581,928	$ —	$ —	$ 77,581,928
Government securities	—	7,409,895	—	7,409,895
Debt securities	—	6,419,533	—	6,419,533
Commercial paper	—	16,479,542	—	16,479,542
Total marketable securities	77,581,928	30,308,970	—	107,890,898
Total cash equivalents and marketable securities	$ 133,058,631	$ 32,803,770	$ —	$ 165,862,401

The following table summarizes the Company's cash equivalents measured at fair value on a recurring basis as of December 31, 2025:

	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market	$ 105,330,208	$ —	$ —	$ 105,330,208
U.S. Treasuries	1,992,340	—	—	1,992,340
Government securities	—	9,222,990	—	9,222,990
Commercial paper	—	11,827,667	—	11,827,667
Total cash equivalents	$ 107,322,548	$ 21,050,657	$ —	$ 128,373,205
Marketable securities:				
U.S. Treasuries	$ 44,276,965	$ —	$ —	$ 44,276,965
Government securities	—	11,945,540	—	11,945,540
Debt securities	—	10,038,420	—	10,038,420
Commercial paper	—	22,108,505	—	22,108,505
Total marketable securities	44,276,965	44,092,465	—	88,369,430
Total cash equivalents and marketable securities	$ 151,599,513	$ 65,143,122	$ —	$ 216,742,635

There have been no changes to the valuation methods during the nine months ended September 30, 2026. There were no transfers between Level 1 and Level 2 in either of the periods and the Company had no financial assets or liabilities that were classified as Level 3 at any point during the nine months ended September 30, 2026.

Note 5 – Property and Equipment, net

Property and equipment, net consisted of the following:

	September 30, 2026	December 31, 2025
Computer equipment	$ 733,801	$ 596,917
Furniture and fixtures	98,628	98,628
Lab equipment	1,315,784	1,309,070
Leasehold improvements	315,297	298,941
Construction in progress	—	37,500
Total	2,463,510	2,341,056
Accumulated depreciation and amortization	(1,654,558)	(1,402,575)
Property and equipment, net	$ 808,952	$ 938,481

Depreciation and amortization expense totaled $86,127 and $78,841 for the three months ended September 30, 2026 and 2025, respectively. Depreciation and amortization expense totaled $251,983 and $248,628 for the nine months ended September 30, 2026 and 2025, respectively.

Note 6 – Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2026	December 31, 2025
Accrued professional services	$ 252,372	$ 735,772
Accrued employee expenses	3,532,834	4,245,563
Accrued research and development expenses	3,620,511	2,747,306
Accrued other expenses	92,420	113,726
Total	$ 7,498,137	$ 7,842,367

Note 7 - Common Stock

The Company had 200,000,000 authorized shares of Class A common stock, $0.001 par value per share as of September 30, 2026 and December 31, 2025 of which 64,763,155 and 64,648,230 were issued and outstanding, respectively. The holders of Class A common stock are entitled one vote for each share of common stock. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the Preferred Stockholders and on a proportionate basis with holders of Class B common stock.

The Company had 20,000,000 authorized shares of Class B common stock, $0.001 par value per share as of September 30, 2026 and December 31, 2025, of which no shares have been issued nor are outstanding. The holders of Class B common stock have no voting rights. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the preferred stockholders and on a proportionate basis with holders of Class A common stock.

2022 Shelf Registration Statement & 2022 ATM Program

On August 10, 2022, the Company filed a Registration Statement on Form S-3 (File No. 333-266738) (the “2022 Shelf Registration Statement”) with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $200 million for a period of up to three years from the date of its effectiveness on August 19, 2022.

On August 10, 2022, the Company also entered into the 2022 Sales Agreement with the Sales Agent to sell shares of the Company's Class A common stock, par value $0.001 per share, with aggregate gross sales proceeds of up to $50 million, from time to time, through the 2022 ATM Program under the 2022 Shelf Registration Statement. Subject to the terms and conditions of the 2022 Sales Agreement, the Sales Agent may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made through the Nasdaq Global Market, on any other existing trading market for the common stock, to or through a market maker, or, if expressly authorized by the Company, in privately negotiated transactions. The Company or Sales Agent could terminate the 2022 Sales Agreement upon notice to the other party and subject to other conditions. The Company paid the Sales Agent a commission equal to 3.0% of the gross proceeds of any Common Stock sold through the Sales Agent under the 2022 Sales Agreement and provided the Sales Agent with customary indemnification rights. The Company did not sell any shares of common stock under the 2022 ATM Program during the three and nine months ended September 30, 2026. The Company sold 327,355 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $4.27, for aggregate gross proceeds of $1.4 million ($1.3 million net of offering expenses) during the three months ended September 30, 2025. The Company sold 5,164,159 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the nine months ended September 30, 2025.

Issuance costs incurred related to the 2022 Sales Agreement were recorded as deferred offering costs and classified as long-term assets on the balance sheet. The Company had approximately $0.5 million of deferred offering costs as of December 31, 2024 associated with the 2022 Sales Agreement. The deferred offering costs for the 2022 ATM Program were written off in August 2025, after the 2022 Shelf Registration Statement and the 2022 ATM Program expired, the 2022 Sales Agreement was terminated, and the Company entered into the 2025 Sales Agreement related to the 2025 ATM Program (in each case as defined herein).

2025 Shelf Registration Statement & 2025 ATM Program

On August 13, 2025, the Company filed a Registration Statement on Form S-3 (File No. 333-289589) (the "2025 Shelf Registration Statement") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units or any combination thereof in the aggregate amount of up to $300 million for a period of up to three years from the date of its effectiveness on August 20, 2025.

On August 13, 2025, the Company also entered into the 2025 Sales Agreement with the Sales Agent to sell shares of the Company's Class A common stock, par value $0.001 per share, with aggregate gross sales proceeds of up to $100 million, from time to time, through the 2025 ATM Program under the 2025 Shelf Registration Statement. Subject to the terms and conditions of the 2025 Sales Agreement, the Sales Agent may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made through the Nasdaq Global Market, on any other existing trading market for the common stock, to or through a market maker, or, if expressly authorized by the Company, in privately negotiated transactions. The Company or Sales Agent may terminate the 2025 Sales Agreement upon notice to the other party and subject to other conditions. The Company will pay the Sales Agent a commission up to 3.0% of the gross proceeds of any Common Stock sold through the Sales Agent under the 2025 Sales Agreement and has provided the Sales Agent with customary indemnification rights. The Company did not sell any shares of Class A common stock under the 2025 ATM Program during the three and nine months ended September 30, 2026 or September 30, 2025, respectively. In connection with the September 2025 Offering, the Company: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by $1,250,007 (or the Reduced Amount, as defined above), resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. As of September 30, 2026, the Company had aggregate gross sales proceeds capacity of $98.7 million remaining under the 2025 ATM Program.

Issuance costs incurred related to the 2025 Sales Agreement are recorded as deferred offering costs and are classified as long-term assets on the balance sheet at September 30, 2026. The Company had approximately $0.2 million of deferred offering costs as of September 30, 2026 associated with the 2025 Sales Agreement.

August 2025 Private Placement

On August 21, 2025, the Company entered into the August 2025 Purchase Agreement with the purchasers party thereto, pursuant to which the Company agreed to sell securities to such purchasers in the August 2025 Private Placement. The August 2025 Purchase Agreement provided for the sale and issuance by the Company to the purchasers of: (i) an aggregate of 5,251,349 shares of its common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 Pre-Funded Warrants to purchase up to the same number of shares of its common stock, and (iii) an aggregate of 2,848,096 Purchase Warrants to purchase up to the same number of shares of its common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant). On October 6, 2025, certain purchasers from the August 2025 Private Placement exercised an aggregate of 1,077,764 Pre-Funded Warrants previously issued to them pursuant to the August 2025 Purchase Agreement. Each such exercise was made pursuant to the cashless exercise provision of the applicable Pre-Funded Warrant, such that an aggregate of 166 shares of common stock were withheld in lieu of a cash payment of the $0.001 exercise price for each Pre-Funded Warrant, and the exercising purchasers were issued an aggregate of 1,077,598 shares of common stock. Following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of September 30, 2026, no Purchase Warrants had been exercised. As of September 30, 2026, the Company had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

Also on August 21, 2025, in connection with the August 2025 Purchase Agreement, the Company entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with the purchasers in the August 2025 Private Placement. Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC for purposes of registering the resale of the common stock and the shares of common stock issuable upon exercise of the Pre-Funded Warrants and Purchase Warrants (collectively, the “Warrant Shares”) purchased by the purchasers in the August 2025 Private Placement, and any shares of common stock issued as a dividend or other distribution with respect to, in exchange for or in replacement of such common stock or Warrant Shares. On September 3, 2025, the Company filed a Registration Statement on Form S-3 (File No. 333-289997) (the “2025 Resale Registration Statement”) with the SEC in relation to the registration for re-sale of the common stock and Warrant Shares from the August 2025 Private Placement. The SEC declared the 2025 Resale Registration Statement effective on September 8, 2025.

The Purchase Warrants have an exercise price of $5.50 per share of common stock, are exercisable immediately following their issuance, and will expire on September 8, 2030. The Purchase Warrants contain standard adjustments to the exercise price including for stock splits, stock dividends or distributions, certain other dividends or distributions and certain reorganizations. The Purchase Warrants also include certain rights upon the occurrence of a “fundamental transaction” (as described in the Purchase Warrants).

The proceeds received from the sale of equity classified warrants and shares of common stock in a bundled transaction are allocated based on the relative fair values of warrants and shares of common stock with no changes in fair value of warrants recognized after the issuance date.
The Purchase Warrants and Pre-Funded Warrants were classified as a component of stockholders’ equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Purchase Warrants and Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company’s common stock and meet the equity classification criteria. In addition, such Purchase Warrants do not provide any guarantee of value or return. The Company valued the Purchase Warrants at issuance using the Black-Scholes valuation model and allocated proceeds from the sale proportionately to the common stock and Purchase Warrants, of which approximately $3.7 million was allocated to the Purchase Warrants and recorded as a component of additional paid-in-capital.

As of September 30, 2026, the Company had 2,848,096 Purchase Warrants issued and outstanding at an exercise price of $5.50 per share to purchase shares of the Company's common stock.

September 2025 Aventis (Sanofi) Private Placement

On September 24, 2025, the Company entered into the September 2025 Purchase Agreement with Aventis, a wholly-owned subsidiary of Sanofi, pursuant to which the Company agreed to sell securities to Aventis in the September 2025 Private Placement. The September 2025 Purchase Agreement provided for the sale and issuance by the Company to Aventis of an aggregate of 2,708,559 shares of its common stock at a purchase price of $9.23 per share. The Company received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million, and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

September 2025 Offering

On September 26, 2025, the Company completed the September 2025 Offering, pursuant to which it issued and sold 18,959,914 shares of its Class A common stock at an offering price of $9.23 per share, with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by the Company from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

Note 8 - Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders was calculated at September 30, 2026 and September 30, 2025 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (24,192,583)	$ (14,964,875)	$ (54,923,905)	$ (44,444,888)
Denominator - basic and diluted:				
Weighted-average common shares outstanding, basic and diluted	64,714,194	39,670,095	64,690,275	37,077,041
Net loss per share - basic and diluted	$ (0.37)	$ (0.38)	$ (0.85)	$ (1.20)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares) at September 30, 2026 and September 30, 2025:

	Nine Months Ended September 30,	
	2026	2025
Options to purchase common stock	11,693,330	8,326,193
Purchase warrants	2,848,096	2,848,096
Total shares of common stock equivalents	14,541,426	11,174,289

Note 9 – Stock-Based Compensation

During 2015, the Company established the Long Term Incentive Plan (“Incentive Plan”), under which incentive stock options, nonqualified stock options, restricted stock or other awards may be awarded to employees, directors or consultants of the Company. The options typically vest over a four-year period. Upon the effectiveness of the Company’s 2021 Incentive Award Plan (the “2021 Plan”), the Company ceased granting awards under the Incentive Plan. However, the Incentive Plan continues to govern awards outstanding thereunder.

On July 23, 2021, the Company's Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Plan, which became effective on July 29, 2021. The 2021 Plan provides for the grant of incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was initially equal to 2,590,000 plus an annual increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 4% of the aggregate number of shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors. No more than 15,350,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. Shares issued under the 2021 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the 2021 Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2021 Plan. In addition, shares subject to stock options issued under the Incentive Plan may become available for issuance under the 2021 Plan to the extent such stock options are canceled, forfeited, exchanged, settled in cash or otherwise terminated. As of September 30, 2026, there were 743,949 shares available for future issuance under the 2021 Plan.

On July 23, 2021, the Company's Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on July 29, 2021. A total of 250,000 shares of Class A common stock were initially reserved for issuance under this plan. The number of shares of Class A common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 1% of the shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors, provided that not more than 3,340,000 shares of Class A common stock may be issued under the 2021 ESPP. As of September 30, 2026, there were 1,421,203 shares of common stock reserved for future issuance under the 2021 ESPP and 605,887 shares had been granted or purchased under the 2021 ESPP.

On May 21, 2024 (the "Effective Date"), based upon the recommendation of the Compensation Committee of the Company's Board of Directors, the Board of Directors approved an option repricing, in accordance with the 2021 Plan, which repricing was effected on the Effective Date. The repricing applied to options to purchase shares of the Company's Class A common stock with an exercise price per share greater than $3.01 that were held by current employees and certain non-employee service providers under the 2021 Plan (the "Eligible Options"), including Michael Bookman, the Company's Chief Legal Officer.

Options held by Benjamin Zeskind, Ph.D., the Company's President and Chief Executive Officer, Brett Hall, Ph.D., the Company's Chief Scientific Officer, and the non-employee members of the Board were not eligible for the repricing.

As a result of the option repricing, as of the Effective Date, the exercise price of all Eligible Options was reduced to $3.01 per share, which represents approximately two times the closing trading price of the Company's Class A common stock on the Nasdaq Global Market on the Effective Date; however, the exercise price for repriced options would have reverted to the original exercise price for any exercise occurring prior to June 30, 2025 (the "Retention Period"), unless there was a change of control of the Company or the option holder's employment had been terminated (i) by the Company without cause or (ii) by reason of death or disability. The repriced options otherwise remain subject to their existing terms and conditions as set forth in the 2021 Plan and applicable award agreements. As of the Effective Date, outstanding options to purchase 2,986,354 shares were deemed Eligible Options and were repriced such that the exercise price per share for such outstanding options was reduced to $3.01 per share. There were no changes to the number of shares, the vesting schedule or the expiration date of the Eligible Options.

The effect of the option repricing resulted in a total incremental non-cash stock-based compensation expense of $0.6 million, which was calculated using the Black-Scholes option-pricing model, of which $0.2 million of the incremental non-cash stock-based compensation expense is associated with vested repriced options and will be recognized on a straight-line basis through the 13-month Retention Period. The remaining $0.4 million of the incremental non-cash stock-based compensation expense is associated with unvested repriced options and will be recognized as follows: (a) if the Retention Period is greater than the remaining original vesting period of the repriced option, the incremental cost will be amortized on a straight-line basis through the Retention Period end date or (b) if the Retention Period is less than the remaining original vesting term of the repriced option, the incremental cost will be amortized on a straight-line basis over the remaining original vesting period.

During the three and nine months ended September 30, 2026, the Company recognized incremental stock-based compensation expense of $20 thousand and $66 thousand, respectively, associated with the repricing which is included in general and administrative and research and development expense in the condensed consolidated statement of operations and comprehensive loss. During the three and nine months ended September 30, 2025, the Company recognized incremental stock-based compensation expense of $32 thousand and $193 thousand, respectively, associated with the repricing which is included in general and administrative and research and development expense in the condensed consolidated statement of operations and comprehensive loss.

On March 20, 2025, the Company's Board of Directors adopted the Immuneering Corporation 2025 Employment Inducement Award Plan (as amended to date, the "Inducement Award Plan"), without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules. The Inducement Award Plan provides for the grant of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the Inducement Award Plan was initially equal to 500,000 shares. On June 11, 2026, the Company's Board of Directors authorized an amendment to the Inducement Award Plan to increase the number of shares reserved for issuance under the Inducement Award Plan to 2,000,000 shares. Shares issued under the Inducement Award Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the Inducement Award Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the Inducement Award Plan. As of September 30, 2026, there were 1,199,600 shares available for future issuance under the Inducement Award Plan.

The Company recognized stock-based compensation expense of $2,060,993 and $5,325,576 during the three and nine months ended September 30, 2026, respectively. During the three and nine months ended September 30, 2025, the Company recognized stock-based compensation expense of $1,456,080 and $4,673,290, respectively. As of September 30, 2026, compensation expense remaining to be recognized for outstanding stock options was $12,748,533 and to be recognized over a weighted-average period of 2.74 years.

The fair value of options granted is calculated on the grant date using the Black-Scholes option valuation model. Prior to the Company's IPO on August 3, 2021, the Company was a private company and thus lacks 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 and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own publicly traded stock price. For the nine months ended September 30, 2026, the Company granted 3,755,521 shares of stock options at a weighted-average grant date fair value of $4.85.

The Company used the following assumptions in its application of the Black-Scholes option pricing model for grants during the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
	2026	**2025**
Weighted-average risk-free interest rate	3.68% - 5.11%	3.76% - 4.55%
Expected term (in years)	5.49 - 10.00	5.51 - 10.00
Expected dividend yield	0%	0%
Expected volatility	66.85% - 82.80%	65.86% - 67.33%

The following table summarizes the stock option activity during the nine months ended September 30, 2026:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2025	8,250,958	$ 3.83		
Granted	3,755,521	4.85		
Exercised	(39,949)	2.71		
Cancelled	(273,200)	3.66		
Outstanding at September 30, 2026	11,693,330	$ 4.16	7.18	$ 9,020,730
Vested and exercisable at September 30, 2026	6,982,192	$ 4.23	6.01	$ 6,188,744

For the three and nine months ended September 30, 2026 and 2025, the Company recognized share-based compensation expense on the accompanying condensed consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 680,180	$ 602,179	$ 2,013,165	$ 1,945,585
General and administrative	1,380,813	853,901	3,312,411	2,727,705
Total	$ 2,060,993	$ 1,456,080	$ 5,325,576	$ 4,673,290

Note 10 – Commitments and Contingencies

Operating Leases

The Company leases 38,613 square feet of office and laboratory space in San Diego, California, under a lease that terminates on April 30, 2032. As of September 30, 2026, the right-of-use asset balance associated with this lease was $3,039,783.

The Company currently also leases office space in Cambridge, Massachusetts and New York, New York, pursuant to short-term arrangements. In October 2026, the Company executed a one year lease extension for its existing office space in Cambridge, with the new term to commence on December 1, 2026 and end on November 30, 2027. The New York lease was most recently renewed in August 2026, to extend the lease term from October 1, 2026 through September 30, 2027. These lease agreements include or included payments for lease and non-lease components. The Company has elected to not separate such components and these payments were recognized as rent expense.

As of September 30, 2026, total future minimum lease payments for its short-term leases in Cambridge, Massachusetts and New York, New York were $44,837 due in 2026 and $145,483 due in 2027.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at September 30, 2026 were as follows:

	Amount
Remainder of 2026	$ 194,724
2027	784,737
2028	808,278
2029	832,527
2030	857,496
Thereafter	1,184,208
Total future lease payments	4,661,970
Less: imputed interest	(1,127,395)
Total lease liabilities	$ 3,534,575
Lease liabilities	$ 445,496
Lease liabilities, net of current portion	3,089,079
Total lease liabilities	$ 3,534,575

Quantitative information regarding the Company's leases for the nine months ended September 30, 2026 and 2025 is as follows:

	September 30, 2026	September 30, 2025
Lease costs:		
Operating lease cost	$ 559,770	$ 559,770
Short-term lease cost	130,284	104,084
Total lease costs	$ 690,054	$ 663,854
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 567,153	$ 550,638
Operating cash flows from short-term leases	130,284	104,084
	$ 697,437	$ 654,722
Weighted-average remaining lease term - operating leases	5.58 years	6.58 years
Weighted-average discount rate - operating leases	10.0 %	10.0 %

As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

Litigation

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities and may be exposed to litigation in connection with its product candidates and operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses. When it is probable that future expenditures will be made and can be reasonably estimated, the Company will accrue a liability for such matters. Significant judgment is required to determine both probability and estimated amount. The Company is not aware of any material legal matters.

Clinical Research Contracts

The Company may enter into contracts in the normal course of business with contract research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies and other services for the Company's operating purposes. These contracts generally provide for termination with a 30-day notice.

Note 11 – Segments

An operating segment is identified as a component of an enterprise about which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker ("CODM") in making decisions, including regarding resource allocation and assessing performance. The Company's Chief Executive Officer is its CODM.

The Company's CODM uses consolidated single-segment (one) financial information for purposes of: allocating resources, evaluating performance, making operating decisions, setting incentive targets, and planning and forecasting for future periods. The Company's CODM makes such decisions based on consolidated net loss. This measure is used to monitor budget versus actual results to evaluate the performance of the segment. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to deploy these resources across functions and operations (including research and development) that align with the Company's strategic goals. All of the Company's long-lived assets are held in the United States.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Program expenses[1]				
atebimetinib (IMM-1-104)	$ 13,551,216	$ 5,091,491	$ 24,868,813	$ 14,518,757
envometinib (IMM-6-415)	3,135	292,917	32,864	2,195,284
Other programs	2,241,354	1,674,358	6,440,894	4,093,993
Non-program expenses[2]	1,310,934	1,894,410	4,520,103	4,677,209
Employee-related costs	6,534,259	4,892,610	18,683,227	15,216,089
Stock-based compensation expense	2,060,993	1,456,080	5,325,576	4,673,290
Depreciation and amortization expense	86,127	78,841	251,983	248,628
Other segment items[3]	(1,595,435)	(415,832)	(5,199,555)	(1,178,362)
Net loss	$ 24,192,583	$ 14,964,875	$ 54,923,905	$ 44,444,888

(1) Includes direct research and development expenses.
(2) Includes general and administrative expenses, in addition to facilities and other research and development expenses.
(3) Includes interest income and other (income) expense.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and with our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, including the audited consolidated financial statements and notes thereto. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive. We are developing and seeking to commercialize an entirely new category of anti-cancer medicines, Deep Cyclic Inhibitors, which we believe have the potential to be more effective and better tolerated targeted therapies.

Deep Cyclic Inhibition® ("DCI") is a novel mechanism that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while sparing healthy cells through a cadenced, normalized level of signaling. Our Deep Cyclic Inhibitors inhibit clinically-validated core signaling pathways, such as the MAPK pathway. Our novel approach is designed to improve durability and tolerability, and differentiates us from chronically targeted precision therapies, which are generally limited by toxicity, resistance and/or application to specific mutations only.

Our lead product candidate, atebimetinib (IMM-1-104), is an oral, once-daily Deep Cyclic Inhibitor of MEK, designed to improve durability and tolerability across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. We are currently conducting a Phase 3 clinical trial of atebimetinib, which we call the MAPKeeper 301 trial, to evaluate atebimetinib in combination with mGnP in first-line pancreatic cancer patients. We dosed the first patient in the MAPKeeper 301 trial in June 2026.

MAPKeeper 301 is a global Phase 3 registrational trial to evaluate atebimetinib (320 mg once-daily) in combination with mGnP, compared to standard of care GnP alone, in first-line metastatic PDAC. The primary endpoint of MAPKeeper 301 is overall survival, and secondary endpoints include progression-free survival, overall response rate, disease control rate, and quality of life measurements. We plan to enroll a total of approximately 570 patients in MAPKeeper 301, divided equally across the two arms. In October 2026, we announced an increase in the MAPKeeper 301 enrollment target from 510 to approximately 570 patients and that enrollment was ahead of schedule. We expect to maintain the trial's topline data readout currently planned for mid-2028, with the potential to accelerate the timing of the readout.

In January 2026, we announced positive interim response and safety data from our ongoing Phase 2a clinical trial arm evaluating atebimetinib in combination with mGnP in first-line pancreatic cancer patients (the "Phase 2 mGnP Arm"), which is part of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors.

In April 2026, we presented a poster at the American Association for Cancer Research (AACR) annual meeting, which provided further updated circulating tumor DNA data on acquired alterations from cancer patients treated with atebimetinib. Consistent with our DCI hypothesis, the observed absence or scarcity of certain RAS/MAPK resistance alterations in atebimetinib-treated patients suggested that the DCI of MEK may lessen selective pressure that drives resistance, thereby slowing adaptation while preserving MAPK dependence, and potentially preserving the opportunity for therapeutic combinations of atebimetinib within the MAPK pathway and across parallel pathways.

In June 2026, we announced further positive interim response and safety data from the Phase 2 mGnP Arm. We announced that, as of a cutoff date of April 24, 2026 (the "Cutoff Date"), 17.3 month median overall survival ("mOS") was observed in the intent-to-treat population of 55 patients dosed at the 320 mg once-daily dose level of atebimetinib in combination with mGnP (the "320 mg ITT Population"), with median follow-up time of 11.6 months. The standard of care (described below) reported a 8.5 month mOS. As of the Cutoff Date, the median progression free survival ("mPFS") of the 320 mg ITT Population was 8.3 months. As of the Cutoff Date, in response evaluable patients from the 320 mg ITT Population, a 36% (18/50 patients) overall response rate ("ORR") and 82% (41/50 patients) disease control rate ("DCR") was observed. Additionally, as of the Cutoff Date, among the subset of patients from the 320 mg ITT Population for which sufficient weight stability data was available, 84% of such patients either gained weight or else were within 5% of original recorded baseline weight. The reported data included patients from same patient cohort (N=34) as we previously reported in January 2026, as well as an additional 21 patients, together comprising the full 320 mg ITT Population. The estimates of (and other references to) standard of care set forth above with respect to mOS data were reported out directly from the publicly available third-party MPACT pivotal trial data for gemcitabine/nab-paclitaxel. Our Phase 1/2a clinical trial of atebimetinib does not include a head-to-head comparison against any other agents, and caution should be exercised when comparing data across trials.

We also announced that, as of the Cutoff Date, atebimetinib in combination with mGnP continued to be generally well tolerated. As of the Cutoff Date, Grade ≥ 3 treatment-emergent adverse events ("TEAEs") observed in 10% or greater of patients in the 320 mg ITT Population consisted of Anemia (nine patients or 16%) and Neutropenia (ten patients or 18%). Grade ≥ 3 TEAEs observed in less than 10% of patients in the 320 mg ITT Population included Rash (5%), Fatigue (2%), Vomiting (2%), and Oedema Peripheral (2%). No Grade 5 TEAEs were observed in this patient population and no new safety signals were identified.

We expect the following anticipated milestones:

- in the fourth quarter of 2026, dosing the first patient in a clinical trial of atebimetinib in combination with Libtayo® in non-small cell lung cancer patients, with a preliminary data readout expected in late-2027;
- in the fourth quarter of 2026, providing additional pre-clinical data of atebimetinib in combination with anti-PD-1 in non-small cell lung cancer;
- in the first half of 2027, providing additional data from the Phase 2 mGnP Arm;
- in mid-2027, beginning IND-enabling studies for our next DCI product candidate program; and
- in mid-2028, providing a topline data readout from the MAPKeeper 301 trial.

Our development pipeline also includes our additional clinical-stage product candidate envometinib (IMM-6-415) and other pre-clinical research programs, including research focused on validated core cancer-signaling pathways outside of the MAPK pathway.

For the period from inception through 2017, we devoted substantially all of our efforts to business planning, service revenue generation, developing tools to aid in drug discovery, and recruiting management and technical staff. Since 2018, we have focused significant effort on our own internal research and development programs, and since December 2022 have exclusively focused our efforts on such programs. We have financed our operations through service revenues (which have since ceased), the issuance of convertible debt and the sale of convertible preferred stock, common stock and warrants exercisable for common stock.

On December 22, 2021, we completed the acquisition of all outstanding shares of capital stock of BioArkive, Inc., a California corporation ("BioArkive"), for a market value of $8.75 million. BioArkive was a San Diego based contract research organization that previously provided preclinical research services and biosample storage to us and other biotechnology companies. BioArkive was fully integrated into our operations following the acquisition and now exclusively supports our internal preclinical research activities for our oncology pipeline. In connection with the acquisition, we assumed BioArkive's lease agreement obligations.

We did not sell any shares of common stock under the 2022 ATM Program during the three and nine months ended September 30, 2026. The Company sold 327,355 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $4.27, for aggregate gross proceeds of $1.4 million ($1.3 million net of offering expenses) during the three months ended September 30, 2025. The Company sold 5,164,159 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the nine months ended September 30, 2025. We did not sell any shares of common stock under the 2025 ATM Program during the three and nine months ended September 30, 2026 or September 30, 2025, respectively.

On August 21, 2025, we entered into the August 2025 Purchase Agreement with the purchasers party thereto, pursuant to which we agreed to sell securities to such purchasers in the August 2025 Private Placement. The August 2025 Purchase Agreement provided for the sale and issuance by us to the purchasers of: (i) an aggregate of 5,251,349 shares of our common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 Pre-Funded Warrants to purchase up to the same number of shares of our common stock, and (iii) an aggregate of 2,848,096 Purchase Warrants to purchase up to the same number of shares of our common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant); following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of September 30, 2026, no Purchase Warrants had been exercised. As of September 30, 2026, we had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

On September 24, 2025, we entered into the September 2025 Purchase Agreement with Aventis (a wholly owned subsidiary of Sanofi), pursuant to which we agreed to sell securities to Aventis in the September 2025 Private Placement. The September 2025 Purchase Agreement provided for the sale and issuance by us to Aventis of an aggregate of 2,708,559 shares of our common stock at a purchase price of $9.23 per share. We received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

On September 26, 2025, we completed the September 2025 Offering, pursuant to which we issued and sold 18,959,914 shares of our common stock at an offering price of $9.23 per share, with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by us from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

Since our inception, we have had significant annual operating losses. Our net loss was approximately $54.9 million for the nine months ended September 30, 2026 and approximately $56.0 million for the year ended December 31, 2025. As of September 30, 2026, we had an accumulated deficit of approximately $335.2 million and approximately $166.1 million in cash, cash equivalents and marketable securities.

We have not had any internally developed products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development of, obtain regulatory approval for, and successfully bring to market one or more of our internally developed product candidates. If we obtain regulatory approval for any of our internally developed product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources including, without limitation, potential collaborations, licenses or similar arrangements.

Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026 will enable us to fund our development activities and other operations into the fourth quarter of 2028. This update to our cash runway guidance (previously expected into 2029) reflects the anticipated cost impact, among other things, of: a longer than previously projected continuation of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors; the planned increase to and acceleration of the target patient enrollment in the MAPKeeper 301 trial; and commercial readiness activities. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate some or all planned activities to reduce costs.

As of October 29, 2026, the issuance date of the interim condensed consolidated financial statements for the three and nine-months ended September 30, 2026 included elsewhere in this Quarterly Report on Form 10-Q, based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our development activities and other operations into the fourth quarter of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

Components of Our Results of Operations

Operating Expenses

Our operating expenses consist of: (i) research and development expenses, and (ii) general and administrative expenses.

Research and Development

Research and development expenses account for a significant portion of our total operating expenses. Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of our research platform, product candidates, discovery efforts and preclinical and clinical activities related to our program pipeline.

Our direct costs include:

- program-specific expenses incurred under agreements with third-party CROs and other vendors that conduct our preclinical and clinical activities on our behalf, including clinical trial sites that conduct research and development activities on our behalf;
- laboratory expenses related to the execution of discovery programs, preclinical studies and clinical trials; and
- costs related to production of clinical and preclinical materials, including fees paid to contract manufacturers.

Our indirect costs include:

- personnel-related expenses, consisting of employee salaries, bonuses, benefits and stock-based compensation expense, and recruiting costs for personnel engaged in research and development activities;
- contractor and consulting fees related to the preparation and ongoing support of clinical trials; and
- facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation and amortization, maintenance of facilities, insurance, and other supplies.

We expense research and development costs in the periods in which they are incurred.

Our direct research and development expenses consist of external costs and fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. Such program costs also include the external costs of laboratory and consumable materials and costs of raw materials that are directly attributable to and incurred for any single program. We do not allocate employee costs, contractor/consultant fees, costs associated with our platform development and discovery efforts, payments made under third-party licensing agreements, costs of laboratory supplies and consumable materials that are not directly attributable to any single program, and facilities expenses, including rent, depreciation/amortization and other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Due to the inherently unpredictable nature and numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of any of our product candidates.

The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, such as, without limitation:

- successful completion of preclinical studies and initiation of clinical trials for future product candidates;
- successful enrollment and completion of clinical trials for our current product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA or other applicable regulatory agencies of IND applications and amendments, clinical trial applications and/or other regulatory filings for our product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- making of arrangements with contract manufacturing organizations for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our product candidates following receipt of marketing approvals, if any.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors.

We may never succeed in achieving regulatory approval for any of our product candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' development, which could increase our research and development expenses. We may obtain unexpected results from our preclinical studies and clinical trials. We have in the past and may in the future 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 factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the advancement of preclinical and clinical development.

We expect that our research and development expenses will substantially increase for the foreseeable future as we continue to implement our business strategy, which includes: advancing our product candidates through clinical development (including atebimetinib in our MAPKeeper 301 Phase 3 clinical trial), expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. As of the date of this Quarterly Report on Form 10-Q, we cannot reasonably determine or accurately project total program-specific expenses through commercialization, if such was to occur. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, stock-based compensation, and recruiting costs for personnel in executive, finance, and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services, insurance costs, travel expenses and facility related expenses not otherwise included in research and development expenses.

We expect our general and administrative expenses will increase for the foreseeable future if and as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. We also expect to continue to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and rules and regulations of the Securities and Exchange Commission (“SEC”), Sarbanes-Oxley Act, director and officer insurance costs, and investor and public relations costs.

Amortization of intangible asset

Amortization of intangible asset relates to the technology acquired in the BioArkive acquisition.

Other Income (Expense)

Interest income

Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

Other income (expense)

Other income (expense) consists of the amortization of premiums or accretion of discounts related to our marketable securities.

Results of Operations

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

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 20,721	$ 10,868	$ 9,853	90.7 %
General and administrative	5,059	4,505	554	12.3 %
Amortization of intangible asset	7	7	—	— %
Total operating expenses	25,787	15,380	10,407	67.7 %
Loss from operations	(25,787)	(15,380)	(10,407)	67.7 %
Other income (expense)				
Interest income	1,205	416	789	189.7 %
Other income, net	391	—	391	N/M%
Net loss	**$ (24,191)**	**$ (14,964)**	**$ (9,227)**	**61.7 %**

Research and Development

The following table summarizes the components of our research and development expenses for the periods indicated:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Direct research and development expenses by program:				
atebimetinib (IMM-1-104)	$ 13,551	$ 5,091	$ 8,460	166.2 %
envometinib (IMM-6-415)	3	293	(290)	(99.0)%
Other programs	2,241	1,674	567	33.9 %
Indirect research and development expenses:				
Employee-related costs	3,861	2,820	1,041	36.9 %
Stock-based compensation expense	680	602	78	13.0 %
Facilities and other expenses	322	328	(6)	(1.8)%
Depreciation and amortization expense	63	60	3	5.0 %
Total research and development	$ 20,721	$ 10,868	$ 9,853	90.7 %

Research and development expenses increased by approximately $9.9 million, or 90.7%, to approximately $20.7 million for the three months ended September 30, 2026, as compared to approximately $10.9 million for the three months ended September 30, 2025. The increase of approximately $9.9 million was primarily due to an increase in direct costs of $8.7 million, driven by $8.5 million related to the conduct of the MAPKeeper 301 trial, in addition to increased preclinical spend of approximately $0.6 million, driven by development pipeline activities. The increase in direct research and development expenses was offset by a decrease of approximately $0.3 million in expenses related to the envometinib program, due to the Company's prioritization of the atebimetinib program. The overall increase in research and development expenses was also driven by an increase in indirect expenses of approximately $1.1 million, primarily driven by increased employee-related costs of $1.0 million, increased stock-based compensation costs of $0.1 million, and an increase in depreciation/amortization and facilities and other expenses of $3 thousand.

General and Administrative

The following table summarizes the components of our general and administrative expenses for the periods indicated:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Employee-related costs	$ 2,673	$ 2,073	$ 600	28.9 %
Stock-based compensation expense	1,381	854	527	61.7 %
Professional fees	574	774	(200)	(25.8)%
Facilities and other allocated expenses	80	57	23	40.4 %
Other	351	747	(396)	(53.0)%
Total general and administrative	$ 5,059	$ 4,505	$ 554	12.3 %

General and administrative expenses increased by approximately $0.6 million, or 12.3%, to approximately $5.1 million for the three months ended September 30, 2026, as compared to approximately $4.5 million for the three months ended September 30, 2025. The increase of approximately $0.6 million was primarily driven by a $0.6 million increase in employee-related costs, a $0.5 million increase in stock-based compensation, and a $23 thousand increase in facilities and other allocated expenses, offset by a decrease in professional fees of $0.2 million and a decrease in other expenses of $0.4 million, with such decreases primarily driven by lower public filing costs associated with the various financing efforts from the prior year.

Amortization of Intangible Asset

Amortization of intangible asset was $7,317 for the three months ended September 30, 2026 and 2025. This amortization is related to the technology acquired from the BioArkive acquisition completed in December 2021.

Other Income (Expense)

Interest income from the interest earned on our cash, cash equivalents and marketable securities balances increased by approximately $0.8 million for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025, driven primarily by an increased total cash balance resulting from various financing events in August and September 2025.

Other income for the three months ended September 30, 2026 was $0.4 million, compared to no other income for the three months ended September 30, 2025. This was primarily driven by the accretion of marketable securities during the three months ended September 30, 2026. There were no marketable securities as of September 30, 2025.

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

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 45,363	$ 32,794	$ 12,569	38.3%
General and administrative	14,738	12,807	1,931	15.1%
Amortization of intangible asset	22	22	—	—%
Total operating expenses	60,123	45,623	14,500	31.8%
Loss from operations	(60,123)	(45,623)	(14,500)	31.8%
Other income (expense)				
Interest income	3,648	1,178	2,470	209.7%
Other income	1,552	—	1,552	N/M%
Net loss	**$ (54,923)**	**$ (44,445)**	**$ (10,478)**	**23.6 %**

Research and Development

The following table summarizes the components of research and development expenses for the periods indicated:

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Direct research and development expenses by program:				
atebimetinib (IMM-1-104)	$ 24,869	$ 14,519	$ 10,350	71.3 %
envometinib (IMM-6-415)	33	2,195	(2,162)	(98.5)%
Other programs	6,441	4,094	2,347	57.3 %
Indirect research and development expenses:				
Employee-related costs	10,863	8,873	1,990	22.4 %
Stock-based compensation expense	2,013	1,946	67	3.4 %
Facilities and other expenses	958	985	(27)	(2.7)%
Depreciation and amortization expense	186	182	4	2.2 %
Total research and development	$ 45,363	$ 32,794	$ 12,569	38.3 %

Research and development expenses increased by approximately $12.6 million, or 38.3%, to approximately $45.4 million for the nine months ended September 30, 2026, as compared to approximately $32.8 million for the nine months ended September 30, 2025. The increase of approximately $12.6 million was primarily due to an increase in direct research and development expenses of $10.5 million, driven by a $10.4 million increase in expenses related to the conduct of the MAPKeeper 301 trial, in addition to increased preclinical spend of approximately $2.3 million. This was offset by a decrease of approximately $2.2 million in expenses related to the envometinib program, due to the Company's prioritization of the atebimetinib program. The overall increase to research and development expenses was also driven by an increase of approximately $2.0 million related to indirect research and development expenses. Indirect expenses were driven by an approximately $2.0 million increase associated with employee-related costs, an approximately $0.1 million increase in stock-based compensation expense, and a minor increase in depreciation/amortization and facilities and other expenses, in the aggregate.

General and Administrative

The following table summarizes the components of general and administrative expenses for the periods indicated:

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Employee-related costs	$ 7,820	$ 6,343	$ 1,477	23.3 %
Stock-based compensation expense	3,312	2,728	584	21.4 %
Professional fees	2,402	2,343	59	2.5 %
Facilities and other allocated expenses	219	183	36	19.7 %
Other	985	1,211	(226)	(18.7)%
Total general and administrative	$ 14,738	$ 12,808	$ 1,930	15.1 %

General and administrative expenses increased by approximately $1.9 million, or 15.1%, to approximately $14.7 million for the nine months ended September 30, 2026, as compared to approximately $12.8 million for the nine months ended September 30, 2025. The increase of approximately $1.9 million was due to a $1.5 million increase in employee-related costs, an increase in stock-based compensation expense of $0.6 million, an increase in professional fees incurred for accounting, auditing, legal and tax services of approximately $0.1 million, and an increase in facilities and other allocated expenses of $36 thousand, offset by a decrease in other expenses of approximately $0.2 million primarily driven by lower public filing costs associated with the various financing efforts from the prior year.

Amortization of Intangible Asset

Amortization of intangible asset was $21,950 for the nine months ended September 30, 2026, and 2025. This amortization is related to the technology acquired for the BioArkive acquisition completed in December 2021.

Other Income (Expense)

Interest income increased by approximately $2.5 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025, driven primarily by an increased total cash balance resulting from various financing events in August and September 2025.

Other income for the nine months ended September 30, 2026 was approximately $1.6 million, compared to no other income for the nine months ended September 30, 2025. This was primarily driven by the accretion of marketable securities during the nine months ended September 30, 2026. There were no marketable securities as of September 30, 2025.

Liquidity and Capital Resources

Sources of Liquidity

We finance our operations through the issuance of convertible notes payable, convertible preferred stock, common stock, warrants exercisable for common stock, and the exercise of stock options.

As of September 30, 2026, we had an accumulated deficit of $335.2 million and $166.1 million in cash, cash equivalents and marketable securities. Cash and cash equivalents are comprised primarily of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, reflected in the change in our outstanding accounts payable and accrued expenses.

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates, and we do not expect to generate revenue from sales of any product candidates for the next several years, if at all. To date, our operations have been financed primarily by service revenues (which have since ceased) and proceeds from sales of our debt and equity securities.

On August 10, 2022, we entered into the 2022 Sales Agreement with the Sales Agent to sell shares of our common stock with aggregate gross proceeds of up to $50 million, from time to time, through the 2022 ATM Program. We did not sell any shares of common stock under the 2022 ATM Program during the three and nine months ended September 30, 2026. We sold 327,355 shares of common stock under the 2022 ATM Program, at a weighted average price per share of $4.27, for aggregate gross proceeds of $1.4 million ($1.3 million net of offering expenses) during the three months ended September 30, 2025. We sold 5,164,159 shares of common stock under the 2022 ATM program, at a weighted average price per share of $3.03, for aggregate gross proceeds of $15.6 million ($15.0 million net of offering expenses) during the nine months ended September 30, 2025. In August 2025, the 2022 Shelf Registration Statement and the 2022 ATM Program expired, and the 2022 Sales Agreement was terminated.

On August 13, 2025, we entered into the 2025 Sales Agreement with the Sales Agent, to sell shares of our common stock with aggregate gross proceeds of up to $100 million, from time to time, through the 2025 ATM Program. In connection with the September 2025 Offering, we: (i) reduced the maximum aggregate offering price for sales of shares of common stock pursuant to at-the-market transactions under the 2025 ATM Program by the Reduced Amount, resulting in a new maximum aggregate offering price of up to $98,749,993 under the 2025 ATM Program, and (ii) suspended the 2025 ATM Program and terminated the continuous offering under the 2025 ATM Program, in each case, as to the Reduced Amount. We did not sell any shares of common stock under the 2025 ATM Program during the three and nine months ended September 30, 2026 or September 30, 2025, respectively.

On August 21, 2025, we entered into the August 2025 Purchase Agreement with the purchasers party thereto, pursuant to which we agreed to sell securities to such purchasers in the August 2025 Private Placement. The August 2025 Purchase Agreement provided for the sale and issuance by us to the purchasers of: (i) an aggregate of 5,251,349 shares of our common stock at a purchase price of $3.95 per share, (ii) for certain purchasers, in lieu of common stock, an aggregate of 1,077,764 Pre-Funded Warrants to purchase up to the same number of shares of our common stock, and (iii) an aggregate of 2,848,096 Purchase Warrants to purchase up to the same number of shares of our common stock. The Pre-Funded Warrants were issued for a purchase price equating to $3.949 per Pre-Funded Warrant (which was the per share purchase price for the common stock issued in the August 2025 Private Placement, less the $0.001 per share unfunded exercise price for each Pre-Funded Warrant); following the October 2025 Cashless Exercise, no Pre-Funded Warrants remained issued and outstanding. The Purchase Warrants were issued with an exercise price of $5.50 per share; as of September 30, 2026, no Purchase Warrants had been exercised. As of September 30, 2026, we had received aggregate net proceeds of $23.4 million from the August 2025 Private Placement, after deducting placement expenses of $1.6 million. The August 2025 Private Placement closed on August 26, 2025.

Also on August 21, 2025, in connection with the August 2025 Purchase Agreement, we entered into the Registration Rights Agreement with the purchasers in the August 2025 Private Placement. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC for purposes of registering the resale of the common stock and the Warrant Shares purchased by the purchasers in the August 2025 Private Placement, and any shares of common stock issued as a dividend or other distribution with respect to, in exchange for or in replacement of such common stock or Warrant Shares. On September 3, 2025, we filed the 2025 Resale Registration Statement with the SEC in relation to the registration for re-sale of the common stock and Warrant Shares from the August 2025 Private Placement. The SEC declared the 2025 Resale Registration Statement effective on September 8, 2025.

On September 24, 2025, we entered into the September 2025 Purchase Agreement with Aventis, a wholly-owned subsidiary of Sanofi, pursuant to which we agreed to sell securities to Aventis in the September 2025 Private Placement. The September 2025 Purchase Agreement provided for the sale and issuance by us to Aventis of an aggregate of 2,708,559 shares of our common stock at a purchase price of $9.23 per share. We received aggregate net proceeds of $23.4 million from the September 2025 Private Placement, after deducting placement agent discounts and commissions of $1.5 million and placement costs of $0.1 million. The September 2025 Private Placement closed on September 26, 2025.

Pursuant to the September 2025 Purchase Agreement, we also agreed to (i) notify Aventis within three business days of us engaging in discussions with any third party regarding, or the board of directors authorizing us to pursue or initiate a process to pursue, any transaction that would be reasonably expected to result in a change of control of the Company or an affiliate of the Company (a "Change of Control") or any other license, sale, assignment, transfer, grant or other disposition of the Company's or an affiliate of the Company's rights to research, develop, manufacture, commercialize, or otherwise exploit atebimetinib (a "Covered Transaction" and, collectively, a "Strategic Transaction Process"), (ii) provide Aventis the opportunity to participate in such Strategic Transaction Process subject to customary confidentiality and other undertakings on substantially the same procedural terms and timeframe as other participants, and (iii) for a period of 120 days following the date of the September 2025 Purchase Agreement, not enter into any Covered Transaction or commence, continue, or otherwise engage in any discussions, or negotiate with any third party, to enter into any Covered Transaction (provided that this provision shall not limit the entry by us into, or any engagement in discussion or negotiations with any third party regarding, a Change of Control transaction). These provisions contain customary confidentiality restrictions and limitations on disclosure obligations, and will terminate upon the earlier of: (a) such time as Aventis and its affiliates no longer hold at least 50% of the securities purchased from the Company pursuant to the September 2025 Purchase Agreement, (b) 90 days after the public release of the topline results of the overall survival of the Phase 3 clinical trial of atebimetinib in pancreatic cancer, (c) the liquidation, dissolution or winding-up of the affairs of the Company, or the consummation of any Change of Control or any other deemed liquidation event of the Company and (d) such time as all development activities with respect to atebimetinib have been terminated.

In addition, pursuant to the September 2025 Purchase Agreement, Aventis agreed (i) until the date that is six months after the closing date of the September 2025 Private Placement, to be subject to customary lock-up restrictions with respect to sales of shares of our common stock (or similar transactions with the same economic effect), subject to certain customary exceptions, (ii) until the first anniversary of the closing date of the September 2025 Private Placement, to be subject to stand-still restrictions with respect to acquisitions of shares of our common stock and similar activities, subject to certain customary exceptions and fall-away provisions, and (iii) until the first anniversary of the closing date of the September 2025 Private Placement or such earlier time as the stand-still restrictions shall have fallen away, vote with respect to all voting securities of the Company as to which it is entitled to vote in accordance with the recommendation of a majority of our board of directors.

On September 26, 2025, we completed the September 2025 Offering, pursuant to which we issued and sold 18,959,914 shares of our Class A common stock at an offering price of $9.23 per share, with Leerink Partners LLC and Oppenheimer & Co. Inc. acting as underwriters. The aggregate net proceeds received by us from the September 2025 Offering were $164.1 million, after deducting underwriting discounts and commissions, as well as offering costs of $0.4 million.

As of September 30, 2026, we had contractual obligations related to various leases of $0.2 million for 2026, $0.8 million for 2027, $0.8 million for 2028, $0.8 million for 2029, $0.9 million for 2030 and $1.2 million for the periods thereafter.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our internally developed product candidates as well as add operational, financial and management informational systems and personnel to support our product development. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026 will enable us to fund our development activities and other operations into the fourth quarter of 2028. This update to our cash runway guidance (previously expected into 2029) reflects the anticipated cost impact, among other things, of: a longer than previously projected continuation of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors; the planned increase to and acceleration of the target patient enrollment in the MAPKeeper 301 trial; and commercial readiness activities. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate some or all planned activities to reduce costs.

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Cash Flows

The following table summarizes our sources and uses of cash for the periods indicated:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (51,720)	$ (35,504)
Investing activities	(19,124)	(18)
Financing activities	426	226,941
Net (decrease) increase in cash and cash equivalents	$ (70,418)	$ 191,419

Net Cash Used in Operating Activities

During the nine months ended September 30, 2026, operating activities used approximately $51.7 million of cash, primarily resulting from our net loss of approximately $54.9 million, changes in assets and liabilities of $1.3 million, and accretion of discount of marketable securities of $1.3 million. This was partially offset by stock-based compensation expense of approximately $5.3 million, depreciation of approximately $0.3 million and the reduction in carrying amount of right-of-use assets of approximately $0.3 million.

During the nine months ended September 30, 2025, operating activities used approximately $35.5 million of cash, primarily resulting from our net loss of approximately $44.4 million, partially offset by changes in assets and liabilities of $3.7 million, stock-based compensation expense of approximately $4.7 million, depreciation of approximately $0.2 million and the reduction in carrying amount of right-of-use assets of approximately $0.3 million.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2026, investing activities used approximately $19.1 million of cash, primarily resulting from purchases of marketable securities of $84.0 million and purchases of property and equipment of approximately $0.1 million, offset by maturities of marketable securities of $65.2 million.

During the nine months ended September 30, 2025, investing activities used approximately $18 thousand, primarily resulting from purchases of property and equipment of approximately $18 thousand.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities was approximately $0.4 million, primarily driven by proceeds of approximately $0.3 million from the sale of common stock pursuant to our employee stock purchase plan and $0.1 million from the exercise of stock options.

During the nine months ended September 30, 2025, net cash provided by financing activities was approximately $226.9 million, primarily driven by proceeds of approximately: $15.0 million from the sale of common stock under the 2022 ATM Program, net of commissions; $0.4 million from the sale of common stock pursuant to our employee stock purchase plan; $0.1 million from the exercise of stock options; $25.0 million from the sale of common stock, Pre-Funded Warrants and Purchase Warrants in the August 2025 Private Placement; $25.0 million from the sale of common stock in the September 2025 Private Placement; and $164.5 million from the sale of common stock in the September 2025 Offering, net of underwriting commissions. The above were partially offset by payments of offering and placement costs and expenses, as applicable, of $3.1 million in the aggregate.

Future Funding Requirements

We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. The timing and amount of our operating and capital expenditures will depend largely on:

- the costs and results of our ongoing clinical trials for atebimetinib, and potential future clinical trials for atebimetinib and our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient ("API"), and manufacture of our product candidates and the terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of future commercialization activities, if any, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- our ability to access the private and public capital markets or to obtain financing at commercially reasonable rate;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the costs of operating as a public company; and
- the impacts of ongoing or future pandemics or other widespread adverse health events.

Based on our currently forecasted operating plan, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2028. Based on our recurring losses from operations incurred since inception, our expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations, as of October 29, 2026, the issuance date of the interim condensed consolidated financial statements for the three and nine-months ended September 30, 2026 included elsewhere in this Quarterly Report on Form 10-Q, management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern, and concluded that there are none as it estimates that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these unaudited condensed consolidated financial statements.

Critical Accounting Policies and Use of Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our Annual Report on Form 10-K for the fiscal year ending December 31, 2025. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting policies from those described in our Annual Report on 10-K for the fiscal year ending December 31, 2025.

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our interim condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

As an emerging growth company ("EGC"), under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board, and less extensive disclosure about our executive compensation arrangements.

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 provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we: (i) are no longer an emerging growth company, or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will continue to qualify as an EGC until December 31, 2026, which is the end of the fiscal year following the fifth anniversary of our IPO.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, we are not required to provide this information.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2026. Based on that evaluation, our Principal Executive Officer and our Principal Financial Officer concluded that, as of September 30, 2026, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not currently party to any material legal proceedings.

Item 1A. Risk Factors

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our Class A common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Forward-Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to Our Financial Condition and Capital Requirements

We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products, have not completed any registrational clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a late-stage clinical oncology company with a limited operating history in developing pharmaceutical products which makes it difficult to evaluate our business and prospects in future product development. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to providing computational biology services to pharmaceutical and biotechnology companies, organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights and undertaking research and preclinical studies and clinical trials of our product candidates, including our ongoing clinical trials of atebimetinib (also referred to as IMM-1-104) for the treatment of advanced solid tumors. We have not yet demonstrated our ability to successfully complete any registrational clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability to develop new pharmaceutical products than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies developing products in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.

We have incurred net losses in each reporting period for the past several years, have not generated any revenue from product sales to date and have financed our operations principally through our historical computational biology services to pharmaceutical and biotechnology companies (which have since ceased), the issuance of convertible debt and the sale of our convertible preferred stock, Class A common stock and warrants exercisable for common stock. We have incurred net losses of approximately $54.9 million and $56.0 million for the nine months ended September 30, 2026 and year ended December 31, 2025, respectively. As of September 30, 2026, we had an accumulated deficit of approximately $335.2 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates, from management and administrative costs and from other expenses that we have incurred while building our business infrastructure. We are currently conducting clinical trials for our product candidate atebimetinib for the treatment of advanced solid tumors. Our other product candidates are in earlier stages of drug development. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our current and future product candidates, including atebimetinib, through preclinical and clinical development, and, if approved by the FDA, EMA or other comparable foreign regulatory authorities, commercialization;
- incur manufacturing costs for our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- incur costs in connection with capital raising activities and potential business restructuring activities, if required;
- expand our manufacturing and develop our commercialization efforts, if any; and
- operate as a public company.

The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, achieving market acceptance of any such approved products and receiving reimbursements in amounts above our costs. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product candidate development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, EMA or other regulatory authorities to perform preclinical studies or clinical trials in addition to those currently expected, or if there are any delays in completing our ongoing preclinical studies or clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

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

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

As of September 30, 2026, we had $166.1 million in cash, cash equivalents, and marketable securities. Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our development activities and other operations into the fourth quarter of 2028. Our estimate as to how long we expect our existing cash, cash equivalents, and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. For example, in October 2026, we shortened our previously disclosed cash runway guidance to reflect the anticipated cost impact, among other things, of: a longer than previously projected continuation of our ongoing Phase 1/2a clinical trial of atebimetinib in patients with advanced solid tumors; a planned increase to and the acceleration of the target patient enrollment in the MAPKeeper 301 trial; and commercial readiness activities. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

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

- the initiation, progress, timeline, cost and results of our clinical trials for our product candidates, including our ongoing registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer;
- the initiation, progress, timeline, cost and results of additional research and/or preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities as we advance our product candidates through preclinical and clinical development, and possible commercialization;
- the potential expansion of our current development programs to seek new indications;

- the potential negative impact of widespread adverse economic or health events (including due to military conflict or pandemics) on our business;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost and timing of completion of commercial-scale manufacturing activities, if any;
- 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 on our own; and
- the cost of operating as a public company.

Advancing the development of our product candidates will require a significant amount of capital. Our existing cash, cash equivalents, and marketable securities will not be sufficient to fund all of the activities that are necessary to complete the development and potential commercialization of our product candidates.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. For example in the past, due to macroeconomic conditions including inflation and higher interest rates, the stock price of biotech companies, including ours, generally declined, making fundraising in our industry more difficult and on less favorable terms. Furthermore, additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and potentially commercialize our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts. In that event, we may have to delay, scale back, or eliminate some or all of our operations, sell assets and/or seek other strategic alternatives.

We maintain the majority of our cash, cash equivalents, and marketable securities in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions have in the past impacted and may in the future impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash, cash equivalents, and marketable securities, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

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

We may seek additional capital through a variety of means, including through public or private equity offerings, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, for example as we did in August and September 2025, your ownership interest may be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition to dilution, such financings may result in the imposition of debt covenants, increased fixed payment obligations, other restrictions (including operating restrictions) or other obligations (for example, providing registration or other information rights to certain investors, as we did in connection with private placements of equity securities in 2025) that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

As of December 31, 2025, we had approximately $174.8 million of federal and $56.7 million of state net operating loss carryforwards ("NOLs"), available to offset future taxable income. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period is subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes such as research tax credits to offset future taxable income. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in other ownership changes. If it is determined that we have in the past experienced other ownership changes, or if we undergo one or more ownership changes as a result of future transactions in our stock, which may be outside our control, then our ability to utilize NOLs and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code, and certain of our NOLs and other pre-change tax attributes may expire unused. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs or other tax attributes to offset such taxable income or otherwise reduce any liability for income taxes may be subject to limitations, which could adversely affect our future cash flows.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable with respect to outcomes. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. 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, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities 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 data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive, or be delayed in receiving, regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials, including without limitation with respect to the appropriate dosing in patients or the use of our product candidates as potential combination therapies;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and/or not effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in a clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the United States, European Union or elsewhere;

- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA, EMA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, 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 seriously harm our business.

We may not be able to submit additional INDs or IND amendments or comparable documents in foreign jurisdictions to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We may not be able to submit additional INDs, IND amendments or comparable documents for atebimetinib, for which an IND was previously submitted, or for our other current or potential product candidates on the timelines we expect. We may also experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We have limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval, including, for example, our registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer. We cannot be certain that our ongoing or planned clinical trials or any future clinical trials will be successful. For example, in April 2025 we paused further internal advancement of envometinib (IMM-6-415) and the related Phase 1/2a clinical trial. Further, it is possible that the FDA may refuse to accept, or be delayed in accepting, any or all of our planned NDAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned NDAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for applications in foreign jurisdictions with comparable regulatory agencies, including without limitation the EMA.

We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

In addition, we are substantially dependent on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase, perhaps substantially.

We do not know whether our current or future clinical trials will begin on time or enroll patients on time, or whether our current or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design, implementation or results of our clinical trials, including without limitation with respect to the appropriate or proper escalation of dosing in patients or the use of our product candidates as potential combination therapies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to current or future pandemics or other events outside our control;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate, with the tumor types, and/or at the stage(s) of disease that we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;

- a facility manufacturing our product candidates or any of their components being ordered by the FDA, EMA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- any changes to our manufacturing process that may be necessary or desired;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory or contractual requirements;

- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, EMA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, the occurrence of any public health crisis or similar global events, such as a future pandemic and its variants, could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA, EMA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials (such as MAPKeeper 301) in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, including with respect to healthcare, cybersecurity and data privacy matters, as well as political and economic risks or military conflicts relevant to such foreign countries.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements;

- be required to perform additional preclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;

- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified REMS;

- be subject to the addition of labeling statements, such as warnings or contraindications;

• be sued; or

• experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of an NDA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidates. Regulatory agencies such as the FDA and EMA have substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

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

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

The outcome of preclinical studies and earlier clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future or later-stage clinical trials, such as our registrational trial of atebimetinib in combination with mGnP in first-line pancreatic cancer, will be successful. We do not know whether any of our product candidates will perform in current or future clinical trials as they have performed in preclinical studies or prior clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA, EMA or comparable foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA, EMA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Additionally, the full impact of emerging therapeutic options in indications that we are pursuing or may pursue, for example daraxonrasib in pancreatic and lung cancer, is unclear and may negatively affect the expected timing and/or interpretability of data from our ongoing or future clinical trials (including, without limitation, MAPKeeper 301), or otherwise limit the commercial potential of our current or future product candidates. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

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

From time to time, we may publicly disclose interim, preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line 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 preclinical studies and clinical trials. For example, we disclosed updated interim safety and efficacy data from the Phase 2a portion of our ongoing Phase 1/2a clinical trial of atebimetinib in June 2026. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between top-line, preliminary and/or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the trading price of our Class A common stock.

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

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

As is the case with pharmaceuticals generally, patients have experienced and likely will in the future experience side effects and/or adverse events associated with the use of our product candidates. Results of our preclinical studies and clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with approved or other investigational products, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant drug-related adverse events or other side effects, including those not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, our product candidates, when used in combination with other therapies, may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy or other aggressive treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still negatively impact the success of our clinical trials. Similarly, already critically ill patients that we enroll in our clinical trials have in the past and may in the future experience adverse medical events due to the general gravity or advanced stage of such patients' illnesses, in each case which could adversely affect our clinical trials even though such outcomes are not related or attributable to our product candidates.

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

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the

risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and costlier than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or be forced to or decide to remove the product from the marketplace;
- regulatory authorities may withdraw or change their approvals of that product in one or more countries;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, our clinical trials will compete with other clinical trials for product candidates that focus on the same therapeutic targets as our current and potential future product candidates, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of other developmental or approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;

- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or will not survive the full terms of the clinical trials (including without limitation because they may be late-stage cancer patients); and
- delays or difficulties in enrollment and completion of studies due to ongoing and future pandemics, or other widespread adverse health events.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in our clinical trials compared to alternative treatments, which alternative treatments could impact the interpretability of data from such clinical trials (including, without limitation, MAPKeeper 301);
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not completed large-scale or pivotal clinical trials nor completed the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often changes during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA, EMA or other applicable regulatory authority policy during the period of drug development, clinical trials and regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA and EMA approval processes described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA or EMA approval.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our Disease Cancelling Technology ("DCT") platform and capabilities to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use and expand our DCT platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery, preclinical and clinical development of atebimetinib and other product candidates, it and other product candidates may not be safe or effective for the indications for which we study them in clinical trials, and we may not be able to develop any other product candidates. Our DCT platform is evolving and may not reach a state at which building a pipeline of product candidates is possible.

The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our DCT platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have only generated interim data from the ongoing Phase 1/2a trial of atebimetinib, and otherwise our data for this product candidate is limited to animal models and preclinical cell lines, the results of which may not translate into humans. As a result, it is possible that safety or other adverse events or concerns could negatively affect the development of atebimetinib or our other current or future product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of our technologies, we intend to work closely with the FDA, EMA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA, EMA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA, EMA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA, EMA and other comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at various disease types, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

We intend to develop certain of our current product candidates in combination with other therapies, and may develop our future product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop atebimetinib as a potential biologic/drug combination product, and we may also develop other current or future product candidates as biologic/drug combination products. Additional time may be required to obtain regulatory approval for any of our current or future product candidates if or when they are developed as potential combination products. Any of our product candidates that may be biologic/drug combination products will require coordination within the FDA, EMA and other comparable foreign regulatory authorities for review of their biologic and drug components. Although the FDA, EMA and other comparable foreign regulatory authorities have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates that may be combination products due to regulatory timing constraints and uncertainties in the product development and approval process.

In addition, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or other regulatory approval.

If the FDA, EMA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

If we successfully develop our product candidates, we may seek approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we initially contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Similar considerations exist with respect to the potential use of accelerated approval pathways in other jurisdictions outside of the United States.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success than our product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products.

Third parties with product candidates or products targeting the MAPK pathway may produce negative preclinical or clinical data which may adversely affect public perception of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Certain of our product candidates, including atebimetinib, are based on the DCI of the MAPK pathway as a model of therapeutic intervention. Our DCI approach may not be viewed as distinct from other existing therapies targeting the MAPK pathway, and negative third party data from preclinical studies and/or clinical trials using other MAPK-targeted therapies could negatively impact the perception of the therapeutic use of such product candidates or products on the whole. This could, among other things, negatively impact our ability to enroll patients in clinical trials. The clinical and commercial success of our product candidates will depend in part on the public's and clinical community's acceptance of the use of DCI therapies. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. Adverse events in our clinical trials, or those of our competitors or of academic researchers utilizing MAPK-targeted therapies, even if not ultimately similar or attributable to our DCI product candidates, and the resulting publicity, could result in increased governmental regulation, unfavorable public perception, increased volatility in our stock price, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products, if approved.

Risks Related to Our Business

We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications that we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and we have not yet completed a Phase 3 clinical trial for our lead product candidate atebimetinib. Further, we have only disclosed interim Phase 2a data for atebimetinib, and in April 2025 we paused further internal advancement of envometinib and the related Phase 1/2a clinical trial. Our other product candidates are in earlier stages of drug development. We have invested substantially all of our efforts and financial resources in the identification of targets, preclinical and clinical development of small molecules targeting the MAPK and other pathways in cancer therapy.

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

The success of our current and future product candidates will depend on several factors, including without limitation the following:

- the successful and timely completion of additional preclinical studies;
- the successful initiation, patient enrollment and completion on a timely basis of our ongoing and any future clinical trials (including our ongoing registrational trial of atebimetinib in combination with mGnP in pancreatic cancer), despite any delays including those arising out of ongoing or future pandemics, or other widespread adverse health events;
- maintaining and establishing relationships with CROs and clinical sites for clinical development, both in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of our product candidates, if approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for atebimetinib or any other product candidate we develop, we may not be able to continue our operations.

We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.

We are substantially dependent on our platform, including our proprietary technologies, which are supported by our information technology systems, for significant elements of our drug discovery process, bioinformatics and computational biology software systems, database of information relating to our product candidates and their role in the targeted disease process, amongst others. Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems and proprietary technologies, these elements of our platform are still vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts, and natural disasters. Our information technology systems and proprietary technologies are potentially also vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems and proprietary technologies, failures or significant downtime of these systems could prevent us from conducting research and development activities for our current and future product candidates, and ultimately delay our drug discovery process. Any failure of our information technology systems and proprietary technologies will materially harm our business.

Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future results of operations are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in preclinical studies and clinical trial development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical studies or earlier clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of the product candidates we have or may develop will depend on many factors, including without limitation the following:

- the success of our research methodology in identifying potential indications or product candidates;
- generating sufficient data to support the initiation or continuation of clinical trials;

• obtaining regulatory permission to initiate clinical trials;

• contracting with the necessary parties to conduct clinical trials;

• successful enrollment of patients in, and the completion of, clinical trials on a timely basis;

• the timely manufacture of sufficient quantities of the product candidate for use in clinical trials;

• adverse events in the clinical trials; and

• any potential interruptions or delays resulting from factors related to ongoing or future pandemics, or other widespread adverse health events.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other product candidates.

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

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. We will have to develop our own sales, marketing and supply organization or outsource some or all of these activities to a third party to commercialize our products. If we decide to license our product candidates to others, we may need to rely on the marketing assistance and guidance of those collaborators.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization, if at all. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates, technologies or processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are attempting or may attempt to develop product candidates. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing or emerging therapies with our products.

In particular, there is intense competition in the fields of oncology we are pursuing. We have competitors both in the United States and internationally, including major multinational biopharmaceutical companies, established biotechnology companies, specialty biopharmaceutical companies, emerging and start-up companies, universities and other research institutions. Our product candidates and programs for oncology will compete with products or programs being advanced by certain of these pharmaceutical and biotechnology companies, organizations and institutions. We also compete with these organizations to recruit management, scientists and clinical development and other personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We have chosen to initially address well-validated biochemical targets, and therefore face and expect to continue to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities and experience than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical trials, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, even if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Similar considerations exist with respect to potentially obtaining marketing approvals in other jurisdictions outside of the United States.

Any delay in obtaining, or an inability to obtain, marketing approvals, whether in the United States or internationally, would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

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

Our business could be adversely affected by global or regional economic, political and / or health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, such as those resulting from political instability (such as workforce uncertainty), trade disputes between nations, and the current and future conditions in the global financial markets. For example, the imposition of tariffs by the U.S. government and any retaliatory tariffs imposed in response have created significant uncertainty, including in the amount, applicability and duration of such tariffs. Tariffs impacting the availability or price of resources used to manufacture our current or future product candidates could adversely affect our preclinical studies and clinical trials and, if in the future any of our product candidates are approved, tariffs may also adversely impact the price and / or demand for such approved products. Moreover third-party vendors, including CROs and CMOs upon which we rely, may suffer disruptions in their businesses or experience significant increases in the cost of their goods or services sold (which they may pass through, in part or in whole, to us) due to factors beyond their control, including tariffs. Additionally, if sustained high rates of inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease, and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our research or clinical activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our clinical trials A severe or prolonged economic downturn, political disruption and / or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which political, economic, health and / or financial market conditions could adversely impact our business.

Ongoing and potential future pandemics could adversely impact our business, including our current and future clinical trials, supply chain and business development activities.

The effects of government actions, our own policies or those of third parties to address ongoing pandemics and any future pandemic may negatively impact productivity and slow down or delay our future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. We may also experience delays in receiving approval from regulatory authorities to initiate or conduct our ongoing or planned clinical trials and delays in regulatory review or approval of any NDA or similar foreign filing we may submit following positive results, if any, in a pivotal study for any of our drug candidates. We may also experience operational delays such as delays or difficulties in enrolling patients in our clinical trials; interruption of key clinical trial activities, such as clinical trial site monitoring due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; and changes in local regulations as part of a response to ongoing or future pandemics, which may require us to change the ways in which our clinical trials are conducted and result in unexpected costs, or to discontinue such clinical trials altogether.

While the potential economic impact brought by, and the duration of, ongoing or future pandemics is difficult to assess or predict, there has in the past been (for example, because of COVID-19 and its variants) and could further be a significant disruption of global financial markets due to a pandemic, that may reduce our ability to access capital and negatively affect our liquidity and financial position. In addition, the trading prices for our Company and other biopharmaceutical companies have in the past been volatile due in part to pandemic, and the same may occur in the future.

These and other disruptions in our operations and the global economy, due to ongoing or future pandemics or any other widespread public health crisis, could negatively impact our business, results of operations and financial condition.

Risks Relating to Our Dependence on Third Parties

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

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with investigational drug substance produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves may take to limit the spread of disease from ongoing or future pandemics, including quarantines and shelter-in-place orders. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs may also have an ability to terminate their respective agreements with us for other reasons, including without limitation if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on, and in the future may rely on, third-party datasets and collaborations with third parties to inform patient selection, drug target identification and other bioinformatic and computational biology analyses for our existing product candidates and any future product candidates and for the supply of biomarker companion diagnostics.

We are using bioinformatics, including data analytics, biostatistics and computational biology, throughout our drug discovery and development process, including to identify new target and biomarker opportunities. As part of this approach, we interrogate public and proprietary datasets, including, but not limited to, human tumor genetic information and specific cancer-target dependency networks. We rely on these datasets and data analytics for multiple analyses, including identifying or validating some of our biomarker-target relationships and access to these databases may not continue to be available publicly or through a proprietary subscription on acceptable terms. Our past, present and future use of such datasets could also create potential liabilities for us if the data provided to us contains inherent errors, inaccuracies or artifacts, or if we improperly analyze, handle, store or utilize the data.

Many of our product candidates also rely on the availability and use of commercially available tumor diagnostics panels or data on the prevalence of our target patient population to inform the patient selection and drug target identification for our product candidates. In cases where such biomarker diagnostic is not already commercially available, we expect to establish strategic collaborations for the clinical supply and development of companion diagnostics. If these diagnostics are not able to be developed at a commercially reasonable cost or at all, or if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing our existing product candidates or any future product candidates.

If we decide to establish new collaborations in the future, but are not able to establish those collaborations on a timely basis, on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to, among other things, expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We may face significant competition in seeking appropriate collaborators and the related negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations in the future with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators in the future for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if, for example, the collaborators believe that such competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or other comparable regulatory authority regulations, provide accurate information to such regulators, comply with international, federal and state health care fraud and abuse and compliance laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, submission of false claims, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting/rebating, marketing and promotion, consulting, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Risks Related to Manufacturing

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency.

Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization (if applicable) as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We contract with third parties, including contract manufacturing organizations and consultants, for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or be able to acquire such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we may obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or non-renewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

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

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of ongoing or future pandemics, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our, or a third-party's, failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and timelines, or to comply with cGMP requirements could adversely affect our business in a number of ways, including without limitation:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities, if any, to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates;
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates; and
- our future profit margins.

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

As product candidates progress through preclinical studies and clinical trials to potential marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to international, federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and government price reporting, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

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, clinical investigators, CROs, 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 market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable international, federal and state healthcare laws and regulations include, among others, the following:

- the federal Anti-Kickback Statute, which 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, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, 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, with potential liability including mandatory treble damages and significant per claim penalties per false claim or statement. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Criminal Statute on False Statements Relating to Healthcare Matters, which makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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 Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare and Medicaid Services ("CMS") information regarding payments and other transfers of value to physicians (as defined by statute), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually;

- analogous state and foreign 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 biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

- some state laws require biotechnology companies to report information to state agencies and/or commercial purchasers on the pricing of certain drug products that exceed a certain level as identified in the relevant statute. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians, some of whom have had, have or may have ownership interests in us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid (or analogous programs in jurisdictions outside the United States), integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. For instance, in the U.S., most healthcare providers, including research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder, or collectively, HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the European Union ("EU") General Data Protection Regulation ("GDPR") governs certain collection and other processing activities involving personal data about individuals in the European Economic Area ("EEA"). The GDPR imposes substantial fines for breaches and violations. The 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 GDPR. Further, since January 1, 2021, companies have to comply with the GDPR and also the United Kingdom ("UK") GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR.

The GDPR and UK GDPR regulate cross-border transfers of personal data out of the EEA and the UK respectively. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, including in relation to transfers to the United States. On July 16, 2020, the Court of Justice of the European Union or the CJEU invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal information could be transferred from the EEA (and the UK) to relevant self-certified U.S. entities. The CJEU further noted that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. Successor legislation and regulation to the Privacy Shield have not been, and may never be, widely adopted in practice for data transfers in the biotechnology field. As the enforcement landscape further develops, and supervisory authorities issue further guidance on international data transfers, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; and/or it could otherwise affect the manner in which we provide our services, and could also adversely affect our business, operations and financial condition.

If we or third-party CMOs, CROs or other contractors, consultants or agents fail to comply with applicable federal, state, local or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any such third party's ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could also give rise to liability, breaches of data security or reputational damage.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost, if at all, to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product candidate that we may be able to commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, including without limitation the EEA, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We may generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we will maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the potential use of hazardous materials in the future, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

The FDA or other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

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

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory authority requirements may subject our company to administrative or judicially imposed sanctions, including without limitation:

• delays in or the rejection of product approvals;

• restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;

• restrictions on the products, manufacturers or manufacturing process;

• warning or untitled letters;

• civil and criminal penalties;

• injunctions;

• suspension or withdrawal of regulatory approvals;

• product seizures, detentions or import bans;

• voluntary or mandatory product recalls and publicity requirements;

• total or partial suspension of production; and

• imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA’s, EMA'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, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We currently have a limited set of compliance policies and personnel, and intend to further develop our compliance infrastructure in the future, as our clinical development programs progress. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. For example, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The U.S. government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Disruptions at the FDA, the SEC and other government agencies including those caused by funding shortages, mandated personnel reductions, policy changes or global health concerns 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 (as well as other U.S. agencies and analogous bodies outside the United States) 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 FDA have fluctuated in recent years as a result. In addition, government funding of the FDA, 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, whether domestic or in jurisdictions outside of the United States, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government shut down several times (including for an extended period beginning in October 2025) and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Similarly, incoming administrations have taken and may in the future take measures to reduce personnel at, and funding for, regulatory agencies including the FDA and the SEC. For example, the current administration has issued executive orders that may significantly reduce the federal workforce and could adversely affect the FDA's ability to attract and retain qualified scientific reviewers, which could result in longer review times for our applications. If a prolonged government shut down, funding or personnel reduction, policy change, or other disruption at the FDA occurs, continues to occur and/or worsens, 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, as a public company, future government shutdowns could impact our ability to further access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, initially in response to the global COVID-19 pandemic, the FDA implemented changes to its inspection activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence or emergence of any pandemic or other widespread adverse health event may lead to further inspection delays. Regulatory authorities outside the United States have in the past and may in the future adopt similar restrictions or other policy measures in response to such events. If a prolonged government shutdown occurs or continues, or if global health concerns prevent the FDA, EMA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, EMA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

A fast track designation from the FDA (or similar designation from a comparable foreign regulatory authority), even when granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive regulatory approval.

In February 2024, July 2024 and December 2024, respectively, we announced that the FDA granted fast track designation for atebimetinib for the treatment of patients: with PDAC who have failed one line of treatment; with PDAC in the first-line setting; and with unresectable or metastatic NRAS-mutant melanoma who have progressed on or are intolerant to PD-1/PD-L1 based immune checkpoint inhibitors. Depending on the data from our preclinical studies and clinical trials, we may decide to seek additional fast track designations for atebimetinib or for other product candidates. The fast track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, potential drugs are eligible for fast track designation if they are intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate may have opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

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

Similar considerations as the foregoing exist with respect to any foreign regulatory authority that may grant a comparable designation to any product candidate.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; expanded the types of entities eligible for the 340B Drug Pricing Program; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included the American Rescue Plan Act of 2021, which eliminated the statutory Medicaid drug rebate cap, which was set at 100% of a drug's average manufacturer price as of January 1, 2024. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In July 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, which imposes significant reductions in the funding of the Medicaid program and restrictions for certain groups to access the ACA Marketplace. These changes are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, and may result in an increase in the number of individuals who are unable to access health insurance benefits and medical care, either of which could adversely affect our sales of any product candidate that we potentially commercialize.

Additionally, the Trump administration has pursued a two-fold strategy to reduce drug costs in the U.S. The administration threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. The administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry generally and our business specifically.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Further, it is possible that additional governmental action is taken in response to ongoing or new pandemics or to other widespread adverse health events.

We may be subject to the UK Bribery Act 2010 (the "Bribery Act"), the U.S. Foreign Corrupt Practices Act of 1977, as amended (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, including our research and development, clinical trial, and (if any of our product candidates receives approval) commercial activities, whether conducted in the United States or internationally, may be 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 currently or may in the future do business. The Bribery Act, the FCPA and these other (or similar) laws generally prohibit us, our employees and our 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. We and our partners may operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may 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 may also be subject to other laws and regulations from time to time governing our international operations, including regulations administered by the governments of the United States, the United Kingdom or elsewhere and authorities in the European Union or elsewhere, 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. 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 the United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We may be subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others with which we do business with could subject us to substantial fines, penalties and injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We may be subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States, and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rule-making to impose new export control restrictions on “emerging and foundational technologies” yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including without limitation by: restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export of our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threat of monetary fines and other penalties for non-compliance.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and/or other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize our product candidates, products (if any) and technology may be impaired, and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent, trade secret or other intellectual property protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and, in some cases, abroad related to our product candidates, technology platforms and their uses that are important to our business.

As of February 2, 2026, we had granted and pending patent filings directed to our product candidates and platforms. With respect to atebimetinib, we had global patent filings providing patent protection for the compound expected into at least 2041 and in the United States until 2042, as well as other pending Patent Cooperation Treaty ("PCT") applications that have not yet entered the national phase providing the basis for additional national phase potential patent claims directed to methods of treatment and pharmaceutical compositions expected into at least 2045, if granted (excluding any possible patent term adjustments, extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable). Further, patent prosecution with respect to our pending patent applications related to our product candidates is in many cases in the early stages. With respect to our platform technology, we have granted U.S. patents expiring in 2039 directed to our Disease Cancelling Technology platform (excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable). We filed patent applications related to our platform technology only in the U.S., so it is possible that a competitor may practice outside the U.S. the aspects of our platform technology disclosed in those patent applications. We maintain other aspects of our platform technology as trade secrets, which were not disclosed in those patent applications. There can be no assurance that any of our current and future issued patents and patent applications, if any, owned by us or our future in-licensed patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around, invalidated or rendered unenforceable by third parties, or would effectively prevent others from commercializing competitive products or technologies. In addition, our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology and such third parties practice the technology in countries where such patents have issued. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents may provide protection for any method of use. We cannot be certain that the claims in our pending patent applications related to composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents can protect the claimed uses of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the existence, issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Although we may obtain licenses to issued patents in the United States and foreign countries in the future, we cannot be certain that the claims in future in-licensed U.S. pending patent applications, if any, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in future in-licensed issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our licensors or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we or our potential licensors do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than the patent law typically applied by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also 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 or in all jurisdictions where protection may be commercially advantageous. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment. Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent are issued, and claim scope can be reinterpreted after issuance. Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations and prospects.

It is also possible that we may not identify, or that we may not timely file on identified, patentable aspects of our research and development output before it is too late to obtain patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the USPTO might require that the term of a patent issuing from a pending patent application to be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those from our licensors, if any, and from third parties. We also may require the cooperation of our potential future licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our potential future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we may in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or potential future in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and any future in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review ("PGR"), and/or inter partes review ("IPR"), or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is no prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or our patent claims being narrowed, invalidated or held unenforceable 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, although we seek to enter into non-disclosure and confidentiality agreements with parties who have access to patentable or trade secret aspects of our technology platforms and research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensors, and other third parties, any of these parties may breach such agreements and disclose such aspects or output before a patent application is filed, thereby jeopardizing our ability to seek patent protection or maintain the trade secret status of our technology platforms or research and development output. Moreover, it is possible that we may not enter into non-disclosure and confidentiality agreements with such parties, thereby potentially compromising our confidential information or otherwise subjecting it to potential loss or misuse.

As referenced above, we have filed patent applications directed to our platform technologies that involve certain of our proprietary software modules. Moreover, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, rely on the above-referenced patent applications for protection of certain modules and trade secret protection for other of our software modules. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

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

In the future, we may enter into license agreements under which we are granted rights to intellectual property that may be important to our business. We expect that any future license agreements where we in-license intellectual property would impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we use the licensed intellectual property in an unauthorized manner or are subject to bankruptcy-related proceedings, the licensors may have the right to materially modify the terms of the licenses, such as by rendering currently exclusive licenses non-exclusive, or terminate the licenses, in which event we would not be able to market products covered by the licenses. We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates or platform, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates or platform in the absence of such a license. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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 for commercializing 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. There can be no assurance that we will 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.

In addition, disputes may arise between us and any future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and obligations imposed under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the amounts, if any, we owe to a potential licensor in respect of sublicense fees or income or in respect of backup product;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and its affiliates and sublicensees and by us and our partners and sublicensees.

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

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

The patent protection and patent prosecution for some of our product candidates may be dependent on our future licensors and third parties.

We or our future potential licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our potential future in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future potential licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future potential licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our future potential in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a future potential licensee of third parties, we would rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our future license agreements. We would not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Future potential licensors may have the right to control enforcement of our future potential licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our future licensors. We cannot be certain that our future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our future potential licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents directed to any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our potential licensors and their counsel that took place prior to us assuming control over patent prosecution.

Technology we may acquire or license from various third parties in the future may be subject to retained rights. Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It may be difficult to monitor whether our future licensors may limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe or misappropriate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement or misappropriation of the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our ability to freely make, use, and sell our products without infringing third party rights. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, as well as related to our platform.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or platform may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that others have not filed patent applications for a product candidate or technology covered by our pending patent applications, or that we were the first to file a patent application related to a product candidate or technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates, products (if approved) or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents relating to such technologies. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, identification of third-party patent rights that may be relevant to our product candidates or platform is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party 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. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Further, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

• require us to enter into royalty or licensing agreements, that may not be available on commercially reasonable terms, or at all, or that might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us to date, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary.

Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations.

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

Moreover, if our product candidates or platform are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of such licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

We may be involved in lawsuits to protect or enforce our patents or the patents of our future licensors, which could be expensive, time-consuming and unsuccessful. Further, our future in-licensed issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe or otherwise violate our, or our future licensors', patents, trademarks or other intellectual property. To prevent infringement or other violations, we and/or our future licensors may be required to file claims, which can be expensive and time-consuming. Further, our future licensors may need to file such claims, but elect not to file them. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our future licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or written description, non-patentable subject matter (laws of nature, natural phenomena, or abstract idea), obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor to the USPTO and in good faith. The outcome following such a challenge is unpredictable. With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights, particularly those in a foreign jurisdiction, may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

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

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or our future licensors, or declared by the USPTO or similar proceedings in foreign patent offices, may be necessary to determine the priority of inventions with respect to our or our potential future licensors' patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our, or our licensors', defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would have been insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation increase the uncertainties and costs surrounding the prosecution of our or our future licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As is the case with many other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Further, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our future licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We or our future licensors may be subject to claims challenging the inventorship or ownership of our or our future in-licensed patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we or our future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we or our future licensors are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Our future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our future licensors are not the sole and exclusive owners of any patents we may in-license. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of FDA marketing approval, if any, of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. While an inadvertent lapse, including due to the effect of a widespread adverse health event, our patent maintenance vendors or law firms, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications relating to our product candidates, our competitive position would be adversely affected.

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

In addition to seeking patent protection for some of our technology and product candidates, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position, especially with respect to our technology platform. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a security breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties may require 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.

We have taken steps to protect our trade secrets and unpatented know-how, including entering into non-disclosure and confidentiality agreements with third parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Further, we cannot provide any assurances that all such agreements have been duly executed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business 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, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach, in each case which could materially harm our business.

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

As is common in the pharmaceutical and biotechnology industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information, trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners, prescribers or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

We use third-party open source software, which could negatively affect our ability to offer our solutions and subject us to litigation or other actions.

We use open source software licensed to us by third-party authors under "open source" licenses in our platform and solutions and expect to continue to use such open source software in the future. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or the quality of the code. To the extent that our platform depends upon the successful operation of open source software, any undetected errors or defects in this open source software could prevent the deployment or impair the functionality of our platform, delay introductions of new solutions, result in a failure of our platform, and injure our reputation. For example, undetected errors or defects in open source software could render it vulnerable to breaches or security attacks, and, as a result, possibly make our systems more vulnerable to data breaches. In addition, the public availability of such software may make it easier for others to compromise our platform.

Further, there are uncertainties regarding the proper interpretation of and compliance with open source licenses, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to use such open source software, and consequently to provide or distribute our platform and solutions. Some open source licenses contain express requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use, or grant other licenses to our intellectual property. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar offerings with lower development cost, effort and time and ultimately could result in a loss of our competitive advantages. Alternatively, to avoid the public release of the affected portions of our source code, we could be required to expend substantial time and resources to re-engineer some or all of our software.

Despite our efforts to monitor our use of open source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, devote additional research and development resources to re-engineer our platform, seek costly licenses from third parties, pay monetary damages to the owner of the copyright in the relevant open source software or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and results of operations. In addition, if the license terms for the open source software we utilize change, we may be forced to re-engineer our platform, incur additional costs to comply with the changed license terms or replace the affected open source software. Although we have implemented policies to regulate the use and incorporation of open source software into our platform and solutions, we cannot be certain that such policies will be effective and that we have not incorporated open source software in our platform and solutions in a manner that is inconsistent with such policies.

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

The degree of future protection afforded by intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example and without limitation:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we may own or license;
- we or our potential future licensors might not have been the first to make the inventions covered by the issued patents or patent application that we may own or license;
- we or our potential future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our, or our future licensors', pending patent applications will not lead to issued patents;
- future issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Risks Related to Employee Matters and Managing our Growth

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we may obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that may receive regulatory approval or any such commercialization may experience delays or limitations. Moreover, even if we do successfully enter such arrangements with third parties, any of those third parties may fail to perform in a satisfactory or timely manner, if at all. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical, administrative and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary, including bioinformatics and computational biologist specialists, for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. We currently do not maintain "key person" insurance for any of our executive officers (other than our chief executive officer) or other employees, and such insurance, even if in place, may not be adequate.

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

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

As of September 30, 2026, we had 65 full-time employees, including 47 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, including operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including without limitation:

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

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

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

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

A variety of risks associated with operating internationally could materially adversely affect our business.

Our current international operations relate primarily to clinical trial activities, but our business plans incorporate potential international expansion, for example including the potential engagement with a collaborator based internationally, or upon any of our product candidates receiving regulatory approval (which may never occur). Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability including wars, terrorism and political unrest (for example, the ongoing conflict between Russia and Ukraine, as well as in the Middle East), outbreak of disease (for example, COVID-19 and other pandemics), boycotts, curtailment of trade and other business restrictions;
- increased susceptibility to trade disputes between nations, including from the imposition of tariffs, which may adversely impact operations (such as conducting ex-U.S. clinical trials or sourcing materials internationally);
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales (if any) and activities that may fall within the purview of the FCPA, its books and records provisions, its anti-bribery provisions or other anti-bribery and anti-corruption laws.

Any of these factors, among others, could significantly limit or harm our future international expansion and operations and, consequently, our results of operations.

Acquisitions, joint ventures or other transactions involving third parties could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We have in the past and may in the future acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, licensing arrangements, supply agreements or investments in complementary businesses. We have limited or in some cases no experience in completing such transactions. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including without limitation:

• disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;

• unanticipated liabilities related to acquired companies;

• difficulties integrating acquired personnel, technologies and operations into our existing business;

• diversion of management time and focus from operating our business to acquisition integration or other collaboration challenges;

• increases in our expenses and reductions in our cash available for operations and other uses;

• possible write-offs or impairment charges relating to acquired businesses;

• disputes regarding intellectual property and/or the scope and interpretation of licensing terms; and

• inability to develop a sales force for any additional product candidates.

Potential foreign transactions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Additionally, the anticipated benefit of any such transaction may not materialize. For example, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of additional debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use them in ways that do not improve our results of operations or enhance value, for example by prioritizing the development of certain product candidates and / or medical indications over others that could have been more successful. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and/or delay the development of our product candidates. Additionally, pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

Risks Related to Ownership of Our Class A Common Stock

We may be unable to maintain an active, liquid and orderly trading market for our Class A common stock and, as a result, it may be difficult for you to sell your shares of our Class A common stock.

The market value of our Class A common stock has in the past decreased from time to time, and may in the future decrease from time to time, and you may not be able to resell your shares of our Class A common stock at or above the price you purchased them. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

The price of our stock has been and may in the future be volatile, and you could lose all or part of your investment.

The trading price of our Class A common stock has in the past been, and in the future is likely to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section, elsewhere in this filing, and in our other SEC filings, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions, including the effects of recession or slow economic growth in the U.S. and abroad, interest rates, tariffs, inflation, fuel prices, international currency fluctuations, corruption, political instability, acts of war, acts of terrorism, ongoing or future military conflicts, and ongoing or future pandemics or other public health crises.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our Class A common stock.

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

The trading market for our Class A common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly (as has happened in the past), we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our voting stock and these stockholders will be able to influence us through this ownership position. These stockholders, if they were to vote their shares in the same or a similar manner as one another, may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their Class A common stock, and might affect the prevailing market price for our Class A common stock.

Sales of a substantial number of shares of our Class A and/or Class B common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our Class A and/or Class B common stock, or the perception that these sales might occur, could depress the market price of our Class A common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of Class A common stock that were sold in the initial public offering and shares of Class A common stock that have been or will be sold under any registration statement declared effective by the SEC are, or will be, as applicable, freely transferable without restrictions or further registration under the Securities Act, except for any shares acquired by our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares of our Class A common stock that are outstanding are either unrestricted or restricted as a result of securities laws. In addition, there are shares of Class A common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plans and may become eligible for future sale subject to vesting, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of Class A common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Class A common stock could decline.

In addition, in the future, we may issue additional shares of Class A common stock, or other equity or debt securities convertible into Class A common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Class A common stock to decline.

We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, if ever. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

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

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our Class A common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

• establish a classified Board so that not all members of our Board are elected at one time;

• permit only the Board to establish the number of directors and fill vacancies on the Board;

• provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;

• authorize the issuance of “blank check” preferred stock that our Board could use to implement a stockholder rights plan (also known as a “poison pill”);

- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our Board to unilaterally amend the bylaws (as, for example, the Board did in February 2024);
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

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

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

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

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

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, agents or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risks

Our information technology systems or use of artificial intelligence, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Our information technology systems and those of our current and any future CROs, CMOs and other contractors, consultants, collaborators, agents and third-party service providers, are vulnerable to attack, interruption and damage from computer viruses (e.g. ransomware), cybersecurity threats, malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. If we or our third-party vendors were to experience a significant security breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

We and our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to our trade secrets, health-related or other personal information or other proprietary or sensitive information, it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions, and it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to data privacy and security laws. Notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from past, present or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and potential commercialization of our product candidates could be delayed or halted, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal, local and/or international privacy and security laws.

In addition, we (and likely many of our third-party vendors, agents and other collaborators) are adopting and exploring the use of Artificial Intelligence ("AI") in our business. As an emerging and rapidly evolving technology, our (and, to the extent applicable, our third-party vendors', agents' and other collaborators') use of AI presents risks that could adversely affect our operations, information security and reputation. For example, AI systems may produce inaccurate or flawed outputs due to improper algorithms, or insufficient and/or erroneous training data. Reliance on flawed outputs could result in lower quality decision-making or prevent us from effectively utilizing AI in our business. We may also become vulnerable to operational disruptions if any AI technologies that we use experience downtimes or are compromised by cyberattacks. Moreover, if any of our confidential or proprietary information is integrated into public AI systems, whether purposefully or accidentally, it could result in the loss of confidentiality (including with respect to intellectual property) or other premature disclosure issues that negatively impact our business operations. If we (or our third-party agents and other collaborators) do not effectively implement guardrails and train staff on the safe and proper use of AI, or if staff fail to effectively adhere to established guardrails and training on the use of AI, we may experience adverse effects on our business, including without limitation data breaches, the loss of confidential information (including our intellectual property), unintentional disclosure of personal data, reputational harm, or other misuse of our proprietary information.

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

Additionally, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. See Part I. Item 1C. "Cybersecurity" contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 for additional information.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, military conflict, future pandemics and other events beyond our control, which could harm our business.

Our facilities are located in regions which experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, geopolitical conflicts, military conflict, future pandemics, public health crises or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this and other periodic reports;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

We will remain an emerging growth company until the earliest to occur 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 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Complying with these laws, rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight will be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, rules, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, rules, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with

evolving laws, rules, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, rules, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory or other governmental authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this filing and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

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. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.

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, 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. Inferior 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 stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer (as defined under applicable SEC rules), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

The market price of our Class A common stock has been and may in the future be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

New tax legislation may impact our results of operations and financial condition.

The U.S. government has enacted, and may in the future enact further, significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. For example, the recently enacted Inflation Reduction Act, among other changes, introduced a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations. Additionally, in July 2025, the Act to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14 was enacted, which for example (and among other things) extends certain tax cuts while eliminating certain others. The likelihood and / or potential impact of these or other further changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur, and if they do occur, what their scope will be. If such changes were to be enacted or implemented, we are currently unable to predict the ultimate impact on our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.
(b) Material changes to the procedures by which security holders may recommend nominees to the board of directors.

None.

(c) Insider Trading Arrangements and Policies

During the three months ended September 30, 2026, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

EXHIBIT INDEX

		Incorporated by Reference				Filed/ Furnished Herewith
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	
3.1	Amended and Restated Certificate of Incorporation of Immuneering Corporation	10-Q	001-40675	3.1	9/9/2021	
3.2	Amended and Restated Bylaws of Immuneering Corporation	8-K	001-40675	3.1	2/2/2024	
4.1	Form of Pre-Funded Warrant	8-K	001-40675	4.1	8/25/2025	
4.2	Form of Purchase Warrant	8-K	001-40675	4.2	8/25/2025	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.					**
101.INS	Inline 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 Document.					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.

SIGNATURES

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

IMMUNEERING CORPORATION

Date: October 29, 2026	By:	/s/ Benjamin J. Zeskind
	Name:	Benjamin J. Zeskind, Ph.D.
	Title:	Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)
Date: October 29, 2026	By:	/s/ Andrew Gengos
	Name:	Andrew Gengos
	Title:	Chief Financial Officer and Treasurer (Principal Financial Officer)
Date: October 29, 2026	By:	/s/ Mallory Morales
	Name:	Mallory Morales
	Title:	SVP Finance, Chief Accounting Officer and Assistant Treasurer (Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Benjamin J. Zeskind, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immuneering Corporation;

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

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

4. The registrant's other certifying officer 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 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: October 29, 2026

By:	/s/ Benjamin J. Zeskind
Name:	Benjamin J. Zeskind, Ph.D
Title:	Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Andrew Gengos, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immuneering Corporation;

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

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

4. The registrant's other certifying officer 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 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: October 29, 2026

By: /s/ Andrew Gengos

Name: Andrew Gengos

Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: October 29, 2026

By:	/s/ Benjamin J. Zeskind
Name:	Benjamin J. Zeskind, Ph.D.
Title:	Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: October 29, 2026

By: /s/ Andrew Gengos

Name: Andrew Gengos

Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)