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: 001-43251

Avalyn Pharma Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-2463191**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
105 W First Street	
Boston, Massachusetts	**02127**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206) 707-0340

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.001 par value per share	AVLN	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 November 10, 2026, the registrant had 44,521,494 shares of voting common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements. 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies, clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future research and development programs, nonclinical studies and clinical trials;
- our ability to successfully complete our clinical trials;
- our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates;
- our ability to quickly leverage programs within our target indications and to progress additional programs to further develop our pipeline;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the timing of our investigational new drug application, or IND, submissions;
- the implementation of our strategic plans for our business, programs and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights;
- developments related to our competitors and our industry;
- the success of competing therapies that are or may become available;
- our ability to leverage the clinical, regulatory, and manufacturing advancements to accelerate our clinical trials and approval of product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our ability to identify and enter into future license agreements and collaborations;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- regulatory developments in the United States and foreign countries;
- our commercialization, marketing and manufacturing capabilities;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, or a smaller reporting company;
- our ability to attract and retain key scientific and management personnel; and

- our anticipated cash runway, our financial performance, estimates of our expenses, capital requirements, and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in "Risk Factors" and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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 or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

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

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Investment in our securities involves risk. You should carefully consider the following summary of what we believe to be the principal risks facing our business, in addition to the risks described more fully in Part II. Item 1A, "*Risk Factors*" in this Quarterly Report and other information included in this Quarterly Report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations.

If any of the following risks occurs, our business, financial condition and results of operations and future growth prospects could be materially and adversely affected, and the actual outcomes of matters as to which forward-looking statements are made in this Quarterly Report could be materially different from those anticipated in such forward-looking statements.

- We are a clinical-stage biopharmaceutical company and have incurred significant operating losses since inception and anticipate that we will continue to incur significant operating losses for the foreseeable future. We may never achieve or maintain profitability.
- We will need substantial additional funding. We may be unable to raise capital on acceptable terms, if at all, and, as a result, we may be required to delay, reduce, or eliminate our product development programs or commercialization efforts.
- We are substantially dependent on the success of our lead candidates, AP01 and AP02. If we are unable to advance such product candidates into later-stage clinical development or unable to obtain regulatory approval and commercialize a therapy for the treatment of pulmonary fibrosis, or PF, or experience significant delays in doing so, our business will be materially harmed.
- We are early in our development efforts. If we are unable to successfully develop, receive regulatory approval for and commercialize any product candidate or successfully develop any other product candidate or experience significant delays in doing so, our business will be substantially harmed.
- Targeting PF with inhaled formulations of antifibrotic therapies is novel, and we do not know whether we will be able to successfully develop any inhaled products.
- We have not yet completed all testing of any product candidate in clinical trials. Nonclinical, interim, topline and preliminary results from our nonclinical studies or clinical trials are not necessarily predictive of the results or analyses of such results of later clinical trials. If we cannot replicate the positive results from any nonclinical studies or clinical trials of our current or potential future product candidates that have positive results, or if we suffer any other significant setbacks in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or potential future product candidates.
- If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, and our receipt of necessary regulatory approvals could be delayed or prevented.
- We face substantial competition and we may not be able to compete successfully in this environment.
- The market for our product candidates may be smaller than we estimate.
- The results of clinical trials conducted at clinical trial sites outside the U.S. might not be accepted by the U.S. Food and Drug Administration, or the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.
- We are dependent on licensed intellectual property rights pursuant to the PARI License Agreement (as defined below) relating to the PARI eFlow® Technology and eRapid® Nebulizer System, and we may in the future enter into additional intellectual property licensing agreements on which we could become similarly dependent.
- We intend to deliver AP01 and AP02 and our other product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval.
- If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected.

- Even if any of our product candidates receive marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We may encounter difficulties in managing our growth, which could disrupt our operations..
- We rely on third parties to assist in conducting our clinical trials and nonclinical studies, manufacture our product candidates and seek to establish collaborations on product development and commercialization plans.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AVALYN PHARMA INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts) (Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 145,424	$ 52,315
Marketable securities, current	182,032	86,044
Prepaid expenses and other current assets	6,250	5,201
Total current assets	333,706	143,560
NON-CURRENT ASSETS:		
Property and equipment, net	1,174	792
Operating lease right-of-use asset	1,953	1,530
Marketable securities, noncurrent	59,142	—
Other assets	3,321	2,999
Total noncurrent assets	65,590	5,321
TOTAL ASSETS	$ 399,296	$ 148,881
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 2,698	$ 3,758
Accrued liabilities	9,417	9,889
Operating lease liability	840	444
Total current liabilities	12,955	14,091
NON-CURRENT LIABILITIES:		
Term loan	14,817	—
Operating lease liability, noncurrent	1,274	1,225
TOTAL LIABILITIES	29,046	15,316
COMMITMENTS AND CONTINGENCIES (Note 8)		
REDEEMABLE CONVERTIBLE PREFERRED STOCK		
Series A redeemable convertible preferred stock, $0.001 par value; no shares and 51,213,004 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 49,651,129 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $0 and $49,651 as of September 30, 2026 and December 31, 2025, net of issuance costs of $475, respectively	—	49,176
Series B redeemable convertible preferred stock, $0.001 par value; no shares and 25,210,789 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 25,208,502 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $0 and $35,693 as of September 30, 2026 and December 31, 2025, net of issuance costs of $317, respectively	—	35,376
Series C-1 redeemable convertible preferred stock, $0.001 par value; no shares and 239,092,424 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 239,016,017 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $0 and $175,041 as of September 30, 2026 and December 31, 2025, net of issuance costs of $547, respectively	—	174,494
Series C-2 redeemable convertible preferred stock, $0.001 par value; no shares and 20,316,359 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 20,316,359 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $0 and $11,903 as of September 30, 2026 and December 31, 2025, net of issuance costs of $49, respectively	—	13,406
Series D redeemable convertible preferred stock, $0.001 par value; no shares and 126,346,412 authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 126,036,334 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $0 and $100,363 as of September 30, 2026 and December 31, 2025, net of issuance costs of $594, respectively	—	99,769
STOCKHOLDERS' DEFICIT		
Preferred stock, $0.001 par value; 10,000,000 shares and no shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.001 par value; 700,000,000 and 575,000,000 shares authorized as of September 30, 2026 and December 31, 2025, respectively; 44,389,507 and 1,227,186 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	67	24
Additional paid-in capital	721,999	26,548
Accumulated other comprehensive (loss) income	(994)	134
Accumulated deficit	(350,822)	(265,362)
Total stockholders' equity (deficit)	370,250	(238,656)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 399,296	$ 148,881

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

AVALYN PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
OPERATING EXPENSES:				
Research and development	$ 25,491	$ 22,089	$ 73,109	$ 55,290
General and administrative	7,603	3,234	19,184	10,526
Total operating expenses	33,094	25,323	92,293	65,816
LOSS FROM OPERATIONS	(33,094)	(25,323)	(92,293)	(65,816)
OTHER INCOME (EXPENSE):				
Interest income	3,756	1,793	7,577	4,668
Interest expense	(277)	(1)	(647)	(1)
Other income (expense)	(40)	(53)	(96)	(129)
Total other income	3,439	1,739	6,834	4,538
NET LOSS	$ (29,655)	$ (23,584)	$ (85,459)	$ (61,278)
COMPREHENSIVE LOSS:				
Net loss	$ (29,655)	$ (23,584)	(85,459)	$ (61,278)
OTHER COMPREHENSIVE LOSS:				
Unrealized gains (losses) on marketable securities	(899)	105	(1,128)	(17)
Total other comprehensive income (loss)	(899)	105	(1,128)	(17)
TOTAL COMPREHENSIVE LOSS	$ (30,554)	$ (23,479)	$ (86,587)	$ (61,295)
Net loss per share of common stock, basic and diluted	$ (0.67)	$ (20.34)	$ (3.39)	$ (69.29)
Weighted-average number of common stock used in net loss per share, basic and diluted	44,354,555	1,159,418	25,236,601	884,399

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

AVALYN PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts) (Unaudited)

	Series A		Series B		Series C-1		Series C-2		Series D		Common		Additional	Accumulated Other Comprehensive Income (Loss)	Accumulated	Total
	Preferred Stock		Preferred Stock		Preferred Stock		Preferred Stock		Preferred Stock		Stock		Paid-In			Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital		Deficit	
BALANCES - December 31, 2025	49,651,129	$ 49,176	25,208,502	$ 35,376	239,016,017	$ 174,494	20,316,359	$ 13,406	126,036,334	$ 99,769	1,227,186	$ 24	$ 26,548	$ 134	$ (265,362)	$ (238,656)
Issuance of warrants in connection with Term Loan	—	—	—	—	—	—	—	—	—	—	—	—	184	—	—	184
Stock options exercised	—	—	—	—	—	—	—	—	—	—	5,256	—	25	—	—	25
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	1,193	—	—	1,193
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(122)	—	(122)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(26,869)	(26,869)
BALANCES - March 31, 2026	49,651,129	$ 49,176	25,208,502	$ 35,376	239,016,017	$ 174,494	20,316,359	$ 13,406	126,036,334	$ 99,769	1,232,442	$ 24	$ 27,950	$ 12	$ (292,231)	$ (264,245)
Conversion of preferred stock into common stock upon initial public offering	(49,651,129)	(49,176)	(25,208,502)	(35,376)	(239,016,017)	(174,494)	(20,316,359)	(13,406)	(126,036,334)	(99,769)	23,918,194	24	372,198	—	—	372,222
Issuance of common stock from initial public offering, net of issuance costs of $4,232	—	—	—	—	—	—	—	—	—	—	19,166,667	19	316,599	—	—	316,618
Issuance of common shares upon exercise of warrants	—	—	—	—	—	—	—	—	—	—	15,012	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	2,790	—	—	2,790
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(107)	—	(107)
Stock options exercised	—	—	—	—	—	—	—	—	—	—	780	—	4	—	—	4
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(28,935)	(28,935)
BALANCES - June 30, 2026	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	44,333,095	$ 67	$ 719,541	$ (95)	$ (321,167)	$ 398,346
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	3,096	—	—	3,096
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(899)	—	(899)
Stock options exercised	—	—	—	—	—	—	—	—	—	—	84,771	—	—	—	—	—
Common stock withheld for taxes and net settlement of stock options	—	—	—	—	—	—	—	—	—	—	(28,359)	—	(638)	—	—	(638)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(29,655)	(29,655)
BALANCES - Sept 30, 2026	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	44,389,507	$ 67	$ 721,999	$ (994)	$ (350,822)	$ 370,250

AVALYN PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts) (Unaudited) (Continued)

	Series A Preferred Stock		Series B Preferred Stock		Series C-1 Preferred Stock		Series C-2 Preferred Stock		Series D Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
BALANCES - December 31, 2024	65,213,004	$ 64,738	25,210,789	$ 35,379	239,016,017	$ 174,494	24,207,788	$ 15,686	—	$ —	276,792	$ 5	$ 5,429	$ 202	$ (180,158)	$ (174,522)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	543	—	—	543
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(88)	—	(88)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(17,503)	(17,503)
BALANCES - March 31, 2025	65,213,004	$ 64,738	25,210,789	$ 35,379	239,016,017	$ 174,494	24,207,788	$ 15,686	—	$ —	276,792	$ 5	$ 5,972	$ 114	$ (197,661)	$ (191,570)
Issuance of Series D preferred stock for cash, net issuance costs of $471	—	—	—	—	—	—	—	—	113,468,242	89,884	—	—	—	—	—	—
Preferred stock conversions	(14,000,000)	(14,000)	—	—	—	—	(3,891,429)	(2,280)	—	—	929,824	18	16,262	—	—	16,280
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	1,128	—	—	1,128
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(20,191)	(20,191)
BALANCES - June 30, 2025	51,213,004	$ 50,738	25,210,789	$ 35,379	239,016,017	$ 174,494	20,316,359	$ 13,406	113,468,242	$ 89,884	1,206,616	$ 23	$ 23,362	$ 80	$ (217,852)	$ (194,387)
Options exercised	—	—	—	—	—	—	—	—	—	—	4,333	—	20	—	—	20
Issuance of Series D shares for cash, net of issuance costs of $123	—	—	—	—	—	—	—	—	12,568,092	9,885	—	—	—	—	—	—
Conversion of preferred stock to common stock upon closing of Series D preferred stock financing	(1,561,875)	(1,562)	(2,287)	(3)	—	—	—	—	—	—	16,237	—	1,565	—	—	1,565
Stock based compensation	—	—	—	—	—	—	—	—	—	—	—	—	725	—	—	725
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,584)	(23,584)
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	105	—	105
BALANCES - September 30, 2025	49,651,129	$ 49,176	25,208,502	$ 35,376	239,016,017	$ 174,494	20,316,359	$ 13,406	126,036,334	$ 99,769	1,227,186	$ 23	$ 25,672	$ 185	$ (241,436)	$ (215,556)

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

AVALYN PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands) (Unaudited)

	Nine Months Ended September 30,	
	2026	2025
OPERATING ACTIVITIES:		
Net loss	$ (85,459)	$ (61,278)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	277	28
Non-cash operating lease expense	408	—
Stock-based compensation expense	7,079	2,396
Amortization and accretion of premiums/discounts on marketable securities	(1,460)	(1,711)
Amortization of debt discount and deferred financing costs	38	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(878)	(521)
Other assets	(324)	(203)
Accounts payable	(1,060)	1,210
Accrued liabilities	(472)	2,836
Operating lease liability	(386)	(40)
Net cash used in operating activities	(82,237)	(57,283)
INVESTING ACTIVITIES:		
Purchases of property and equipment	(659)	(92)
Purchases of marketable securities	(241,029)	(109,299)
Proceeds from sale of marketable securities	26,342	—
Maturities of marketable securities	59,890	70,500
Net cash used in investing activities	(155,456)	(38,891)
FINANCING ACTIVITIES:		
Proceeds from initial public offering, net of underwriter discounts and commissions paid during the period	320,850	—
Payment of offering costs	(4,231)	—
Proceeds from the exercise of stock options	29	20
Proceeds from Term loan	15,000	—
Payments of withholding taxes in connection with exercise of options	(638)	—
Payments of issuance costs associated with Term loan	(208)	—
Proceeds from issuance of Series D convertible preferred stock, net of issuance costs	—	99,769
Net cash provided by financing activities	330,802	99,789
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	93,109	3,615
CASH AND CASH EQUIVALENTS:		
Beginning of period	52,315	23,955
End of period	$ 145,424	$ 27,570
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of preferred stock into common stock upon IPO	$ 372,198	$ —
Deferred offering costs transferred to additional paid in capital	4,232	—
Right-of-use assets obtained in exchange for operating lease liabilities	831	1,676
Option exercise through net share settlement	413	—
Warrant value issued as part of Term loan	184	—

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

1. Description of Business

Avalyn Pharma Inc., or the Company or Avalyn, is a clinical-stage biopharmaceutical company developing inhaled medicines to treat rare respiratory diseases, including progressive pulmonary fibrosis, idiopathic pulmonary fibrosis, and other interstitial lung diseases. The Company was incorporated in the state of Delaware on May 27, 2011, and has its headquarters in Boston, Massachusetts.

As used in these consolidated financial statements, unless the context otherwise requires, references to the "Company" or "Avalyn," refer to Avalyn Pharma Inc. and its wholly owned subsidiary, Avalyn Pharma Pty. Ltd.

Risks and Uncertainties

The Company is subject to the risks and challenges associated with other biopharmaceutical companies at a similar stage of development, including dependence on key individuals, successful development of its products and services, dependence on key vendors, compliance with government regulations, protection of proprietary technology, competition from substitute products and services and larger companies which have greater financial resources, technical management, and the ability to secure adequate financing to support future growth. There can be no assurance that any future products or services can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products or services will be successfully marketed, if at all. These factors could have a material adverse effect on the Company's future operating results, financial position and cash flow.

Existing or future products developed by the Company will require approvals or clearances from the U.S. Food and Drug Administration, or the FDA, or other similar international regulatory agencies prior to commercial sales. If the Company were denied or delayed in receiving such approvals or clearances, it would have a material adverse effect on the Company.

Reverse Stock Split

The Company's Board approved a 1-for-19.2417 reverse stock split of its issued and outstanding common stock, which also resulted in a proportional adjustment to the conversion price for each series of its preferred stock, and to the exercise prices and number of outstanding stock options, and warrants, which became effective on April 22, 2026. Accordingly, all shares of common stock, stock options, warrants, and per share information presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split. The per share par value and authorized number of both common and preferred shares were not adjusted as a result of the split.

Initial Public Offering

On May 1, 2026, the Company completed its initial public offering, or IPO, in which the Company sold an aggregate of 19,166,667 shares of its common stock at a public offering price of $18.00 per share, which included 2,500,000 shares of its common stock sold to the underwriters pursuant to the full exercise of their option to purchase additional shares, resulting in aggregate net proceeds of approximately $316.6 million, after deducting underwriter discounts, commissions and other offering expenses. Immediately prior to the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 23,918,194 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were outstanding. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 700,000,000 shares of common stock, par value $0.001 per share, including 500,000,000 shares of voting common stock and 200,000,000 shares of non-voting common stock, of which there were zero shares issued or outstanding as of September 30, 2026; to eliminate all references to the previously-existing series of preferred stock, and authorize 10,000,000 shares of preferred stock, par value $0.001 per share.

Going Concern

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Since its inception, the Company has funded its operations with proceeds from convertible notes, its IPO, and with proceeds from the issuance of Series A, Series B, Series C-1, Series C-2 and Series D preferred stock. The Company has incurred net losses, and utilized cash, cash equivalents, and marketable securities in operations since inception, has an accumulated deficit as of September 30, 2026 of $350.8 million, and expects to incur future additional losses. As of September 30, 2026, the Company had cash, cash equivalents,

and marketable securities of $386.6 million. The Company has determined that its existing cash, cash equivalents, and marketable securities will be sufficient to fund the Company's operating expenses and capital expenditures requirements for at least 12 months from the issuance date of these consolidated financial statements.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2026, and the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2026 and 2025, consolidated statements of changes in redeemable convertible preferred stock and stockholders' equity (deficit), and consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025, are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position as of September 30, 2026, the results of its operations for the three and nine months ended September 30, 2026 and 2025, and its cash flows for the nine months ended September 30, 2026 and 2025. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2026 and 2025, are also unaudited. The results for the three and nine months ended September 30, 2026 and 2025 are not necessarily indicative of results to be expected for the year ending December 31, 2026, or for any other subsequent period.

2. Summary Of Significant Accounting Policies

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited consolidated financial statements for the year ended December 31, 2025 and notes thereto, included in the Company's registration statement on Form S-1.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and applicable rules and regulations of the U.S. Securities and Exchange Commission, or the SEC, regarding interim financial reporting. Accordingly, they do not include all disclosures normally required in annual consolidated financial statements prepared in accordance with U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and ASUs of the Financial Accounting Standards Board, or FASB.

Principles of Consolidation

The consolidated financial statements include the accounts of Avalyn Pharma Inc. and its wholly owned subsidiary, Avalyn Pharma Pty. Ltd. All intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with U.S. GAAP.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expense during the reporting period. The Company bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Management evaluates its estimates and assumptions on an ongoing basis. Changes in estimates are recorded in the period in which they become known. Significant estimates and assumptions relied upon in preparing these financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs, and the valuation of common stock and related stock-based compensation expense. The Company's actual results may differ from these estimates under different assumptions or conditions.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting, and other third-party fees that are incremental costs and directly associated with in-process equity and debt financings as deferred offering costs within non-current assets on the consolidated balance sheets until such time the equity and debt financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction to the carrying value of the preferred stock or, for the issuances of common stock, in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of comprehensive loss. As of September 30, 2026 and December 31, 2025, there were deferred offering costs of $0.2 million and $0.3 million, respectively.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, or ASU 2024-03, which requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as

disclosures about selling expenses. The requirements of ASU 2024-03 are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently in the process of evaluating the effects of this pronouncement on its related disclosures.

3. Marketable Securities

The following tables summarize the amortized cost and estimated fair value of the Company's marketable securities, which are considered to be available-for-sale investments (in thousands):

	September 30, 2026			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, current:				
U.S. Treasury securities	$ 61,896	$ —	$ (157)	$ 61,739
Commercial paper	92,847	—	(232)	92,615
Corporate debt securities	24,270	—	(88)	24,182
U.S. government agency debt securities	3,503	—	(6)	3,497
Marketable securities, long-term:				
U.S. Treasury securities	45,007	—	(368)	44,639
Corporate debt securities	11,650	—	(114)	11,536
U.S. government agency debt securities	2,995	—	(29)	2,966
Total marketable securities	$ 242,168	$ —	$ (994)	$ 241,174

	December 31, 2025			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, current:				
U.S. Treasury securities	$ 30,049	$ 75	$ —	$ 30,124
Commercial paper	30,699	26	—	30,725
Corporate debt securities	25,162	33	—	25,195
Total marketable securities	$ 85,910	$ 134	$ —	$ 86,044

As of September 30, 2026, all marketable securities held by the Company had remaining contractual maturities of one year or less, except for a portion of the U.S. treasuries, corporate debt securities and U.S. government agency debt securities, with a fair value of $44.6 million, $11.5 million and $3.0 million, respectively, that had remaining contractual maturities of greater than one year. As of December 31, 2025, all marketable securities held by the Company had remaining contractual maturities of one year or less.

The Company has determined that there were no material changes in the credit risk, therefore, no impairment was recognized on its debt securities.

4. Fair Value Measurements

The following tables present information about the Company's financial instruments that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market accounts	$ 36,216	$ —	$ —	$ 36,216
Marketable securities:				
U.S. Treasury securities	—	106,378	—	$ 106,378
Commercial paper	—	92,615	—	$ 92,615
Corporate debt securities	—	35,718	—	$ 35,718
U.S. government agency debt securities	—	6,463	—	$ 6,463
Total	$ 36,216	$ 241,174	$ —	$ 277,390

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market accounts	$ 16,245	$ —	$ —	$ 16,245
Marketable securities:				
U.S. Treasury securities	—	30,124	—	30,124
Commercial paper	—	30,725	—	30,725
Corporate debt securities	—	25,195	—	25,195
Total	$ 16,245	$ 86,044	$ —	$ 102,289

As of September 30, 2026 and December 31, 2025, the Company had cash equivalents consisting of money market accounts classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustments. The Company classifies its investments in U.S. Treasury securities (Treasury bills, Treasury notes, and Treasury bonds), commercial paper, U.S. government agency debt, and corporate debt securities as Level 2 instruments. The Company estimates the fair value of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize standard industry valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly to estimate fair value. These inputs include market pricing based on real time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.

During the three and nine months ended September 30, 2026 and 2025, there were no transfers or reclassifications between fair value measurement levels of financial assets or liabilities.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Prepaid research and development expenses	$ 3,079	$ 3,908
Interest receivable	1,549	537
Prepaid insurance	80	61
Deposits	—	50
Deferred financing costs	221	255
Other prepaid expenses	1,321	390
Total prepaid expenses and other current assets	$ 6,250	$ 5,201

6. Property and Equipment

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

	September 30, 2026	December 31, 2025
Computers, software, and office equipment	$ 154	$ 154
Furniture and fixtures	288	—
Lab equipment	—	10
Leasehold improvements	980	—
Construction in progress	73	682
Total property and equipment	1,495	846
Less: Accumulated depreciation	(321)	(54)
Property and equipment, net	$ 1,174	$ 792

Total depreciation expense was $104.4 thousand and $277.0 thousand for the three and nine months ended September 30, 2026, respectively, and $9.0 thousand and $28.0 thousand for the three and nine months ended September 30, 2025, respectively.

7. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Employee compensation and vacation accrual	$ 4,241	$ 4,292
Accrued legal and professional fees	868	1,200
Accrued research and development costs	4,308	4,397
Total accrued liabilities	$ 9,417	$ 9,889

8. Commitments And Contingencies

Leases

In September 2025, the Company relocated its headquarters to Boston, Massachusetts and entered into a non-cancelable operating sublease in Boston, or the Boston Sublease, to rent out 8,774 square feet of office space. The lease commenced on September 2, 2025, at which time the Company recognized a right-of-use, or ROU, asset and corresponding lease liability of $1.7 million. The lease term is 41 months with rental payments beginning four months after the lease commencement. In addition to base rent, the Company will reimburse the landlord for certain operating expenses under the terms of the lease. The Company has the option to extend the lease one time for an additional 3-year period, subject to the terms therein; however, the exercise of the option to extend the lease term was not determined to be reasonably certain, and the Company will therefore recognize lease expense through the expiration of the initial lease term ending in January 2029.

In June 2026, the Company entered into an amendment to the Boston Sublease. Pursuant to the amendment, the Subleased Premises were expanded to include an additional 4,934 rentable square feet located on the second floor of the building, which expires in January 2029. The lease commenced on June 29, 2026, at which time the Company recognized an additional ROU asset and corresponding operating lease liability of $0.8 million, including $0.3 million of current lease liability and $0.5 million of noncurrent lease liability. The Company has the option to extend the lease one time for an additional 3-year period, subject to the terms therein; however, the exercise of the option to extend the lease term was not determined to be reasonably certain, and the Company will therefore recognize lease expense through the expiration of the initial lease term ending in January 2029.

Lease liabilities are measured by calculating the present value of remaining lease payments under the lease arrangement. Since the rates implicit in our leases are not readily determinable, the Company uses estimated incremental borrowing rates in determining the discount rate used to calculate the present value of remaining lease payments. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term equal to the lease term in a similar economic environment. The incremental borrowing rate is based on the information available at commencement date. As the Company has no relevant external borrowings, the incremental borrowing is a hypothetical rate based on our understanding of what our credit rating would be and adjusted to reflect a collateralized borrowing.

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

	September 30, 2026	December 31, 2025
Operating lease right-of-use asset, noncurrent	$ 1,953	$ 1,530
Operating lease liability, current	840	444
Operating lease liability, noncurrent	1,274	1,225

The Company incurred total operating lease expenses of $0.3 million and $0.6 million during the three and nine months ended September 30, 2026, respectively, and $48.5 thousand during the three and nine months ended September 30, 2025. The Company incurred an immaterial amount of expense related to variable lease costs during the three and nine months ended September 30, 2026 and no expense related to variable lease costs during three and nine months ended September 30, 2025.

Future minimum lease payments under non-cancelable leases were as detailed below (in thousands):

	September 30, 2026
2026	$ 240
2027	986
2028	1,016
2029	85
Total undiscounted future minimum lease payments	2,327
Less: Imputed interest	(213)
Total operating lease liabilities	$ 2,114

Cash paid for amounts included in the measurement of operating lease liabilities were $0.2 million and $0.5 million for the three and nine months ended September 30, 2026, respectively, and $51.2 thousand during the three and nine months ended September 30, 2025.

During the three and nine months ended September 30, 2026 and 2025, the Company did not recognize any impairment losses on its ROU assets.

Legal Proceedings

From time to time, the Company is subject to various claims that arise in the ordinary course of business. The Company is not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business, financial position, results of operations, or cash flows of the Company.

9. Common Stock

The Company's certificate of incorporation, as amended and restated, authorizes the Company to issue 700,000,000 shares of common stock, par value $0.001, as of September 30, 2026, of which 500,000,000 is voting and 200,000,000 is designated as non-voting. The holders of voting common stock are entitled to one vote for each share of common stock held.

The number of shares of common stock that have been reserved for the potential conversion of preferred stock, exercise of outstanding stock options granted and warrants, and stock options available for grant under the Company's 2026 Equity Incentive Plan, or the 2026 Plan, as of September 30, 2026, and the Company's 2022 Equity Incentive Plan, or the 2022 Plan, as of December 31, 2025, are as follows:

	September 30, 2026	December 31, 2025
Conversion of Series A	—	2,580,370
Conversion of Series B	—	1,310,082
Conversion of Series C-1	—	12,421,759
Conversion of Series C-2	—	1,055,847
Conversion of Series D	—	6,550,136
Outstanding common stock options	6,799,641	4,088,900
Outstanding common stock warrants	222,830	222,830
Common stock options available for grant	1,694,799	48,911
Total	8,717,270	28,278,835

10. Stock Option Plan

Stock Option Plans

On February 10, 2022, the Company adopted the 2022 Plan, which has been subsequently amended. The 2022 Plan provides for the issuance of incentive and nonqualified common stock options to employees, directors, and certain consultants. The 2022 Plan is administered by the Board which determines the awards to be granted, including the number of common shares subject to the awards, the exercise price, and the vesting schedule. In connection with the IPO, the Company adopted its 2026 Plan, at which time shares ceased to be available for issuance under the 2022 Plan.

Subsequent to the effectiveness of the 2026 Plan, the shares of common stock underlying any awards under the 2022 Plan that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other

than by exercise) and shares withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding will be added to the shares of common stock available for issuance under the 2026 Plan.

2026 Equity Plans

In April 2026, the Board and the Company's stockholders adopted and approved the 2026 Plan, which became effective on April 28, 2026, the date immediately preceding the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 Plan initially reserved 4,160,000 shares of common stock for future issuances and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 Plan. The shares reserved for future issuance under the 2022 Plan ceased to be available for issuance at the time the 2026 Plan became effective. Any shares underlying outstanding stock awards granted under the 2022 Plan that subsequently expire or are repurchased, forfeited, canceled, or withheld will return to the 2026 Plan and be reserved and available for issuance. The Company granted 2,387,705 of common stock options subject to service-based vesting to certain executive officers, directors, and employees at the time of effectiveness of the 2026 Plan with an exercise price equal to $18.00 per share.

In April 2026, the Board and the Company's stockholders adopted and approved the 2026 Employee Stock Purchase Plan, or the 2026 ESPP, which became effective on April 28, 2026, the date immediately preceding the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 ESPP initially reserved 370,000 shares of common stock for future issuance and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 ESPP.

Employee Stock Options Valuation

The Company estimates the fair value of stock options on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires estimates of highly subjective assumptions, which affect the fair value of each stock option. The assumptions used to determine the fair values of stock options granted to employees, directors, and certain consultants are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Risk-free interest rate	4.5%	3.7%	4.0 - 4.5%	3.7 - 4.1%
Expected life of options (in years)	6.0 - 6.1	5.9 - 6.1	5.6 - 6.1	5.9 - 6.1
Expected volatility of underlying stock	73.3 - 73.8%	65.5 - 65.7%	69.7 - 79.6%	65.5 - 66.6%
Expected dividend yield	—%	—%	—%	—%

The following table summarizes the stock option activity:

	Number of Stock Options	Weighted Average Exercise Price (per share)	Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	4,088,900	$ 4.92	8.20	$ 444
Options granted	2,968,791	17.32		
Options exercised	(90,806)	4.87		
Options forfeited	(160,794)	10.41		
Options expired	(6,450)	4.65		
Outstanding as of September 30, 2026	6,799,641	$ 10.20	8.34	124,527
Options exercisable as of September 30, 2026	2,757,080	$ 6.00	7.04	$ 62,001

The weighted-average grant date fair value of stock options granted in the three and nine months ended September 30, 2026 was $20.35 and $12.10, respectively. The weighted-average grant date fair value of stock options granted in the three and nine months ended September 30, 2025 was $2.99 and $3.00, respectively. The total intrinsic value of stock options exercised during both the three and nine months ended September 30, 2026 was $2.7 million. The total intrinsic value of stock options exercised during both the three and nine months ended September 30, 2025 was insignificant. As of September 30, 2026, total stock-based compensation cost not yet recognized related to unvested stock options was $34.7 million, which is expected to be recognized over a weighted-average period of 2.97 years. Stock-based compensation expense recognized in the accompanying consolidated statements of comprehensive loss for the three and nine months ended September 30, 2026 and 2025, included the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
General and administrative	$ 1,891	$ 502	$ 4,488	$ 1,836
Research and development	1,205	223	2,591	560
Total	$ 3,096	$ 725	$ 7,079	$ 2,396

11. Segment Information

The Company operates and manages its business as one operating segment and one reportable segment, which is focused on developing targeted therapies to treat rare lung diseases. The chief operating decision maker, or CODM, manages the Company's operations on a consolidated basis, assesses performance for the operating segment and decides how to allocate resources based on consolidated operating results, which is reported on the consolidated statements of comprehensive loss. The CODM is the Company's Chief Executive Officer.

The monitoring of budgeted versus actual results is used in assessing the performance of the operating segment and in establishing resource allocation across the organization. Depreciation expense, amortization expense, stock-based compensation expense, and non-cash lease expense are significant noncash items included in net loss and reported on the consolidated statements of cash flows. The measure of segment assets is reported on the consolidated balance sheets as total assets. Expenditures for additions to long-lived assets, which include purchases of property and equipment, are included in total assets, reviewed by the CODM, and are reported on the consolidated statements of cash flows.

The following table represents information about segment loss and significant segment expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Direct research and development expenses by program:				
AP01	$ 11,964	$ 13,789	$ 38,719	$ 37,248
AP02	6,384	3,405	16,072	5,506
AP03	1,208	1,257	2,268	2,130
Unallocated research and development expenses:				
Personnel-related (excluding stock-based compensation)	4,022	2,914	11,963	8,688
Facility and information technology allocated expenses and other research and development costs	708	499	1,496	1,155
General and administrative expenses:				
Personnel-related (excluding stock-based compensation)	2,788	1,579	7,610	4,745
Facility expenses and information technology	549	259	1,370	550
General corporate expenses and professional fees	2,272	887	5,440	3,369
Other segment items [1]	(240)	(1,005)	521	(2,113)
Net loss	$ 29,655	$ 23,584	$ 85,459	$ 61,278

(1) For the three months ended September 30, 2026 and 2025, other segment items consist of $2.7 million and $1.2 million of interest income, respectively, $1.1 million and $0.7 million of accretion of marketable securities, respectively, $3.1 million and $0.7 million of stock-based compensation expense, respectively, $0.2 million and zero of interest expense, respectively, and $145.6 thousand and $63.6 thousand of depreciation expense and other expenses, respectively. For the nine months ended September 30,

2026 and 2025, other segment items consist of $6.1 million and $3.0 million of interest income, respectively, $1.5 million and $1.7 million accretion of marketable securities, respectively, $7.1 million and $2.4 million of stock-based compensation expense, respectively, $0.6 million and zero of interest expense, respectively, and $374.0 thousand and $157.3 thousand of depreciation expense and other expenses, respectively.

Direct research and development expenses by program consist primarily of costs paid to third-parties including contract research organizations, or CROs, contract manufacturing organizations, or CMOs, consultants, advisors, and other clinical study-related vendors.

Unallocated research and development expenses consist primarily of personnel-rated expenses and allocated information technology and facility expenses and other research and development related costs, excluding non-cash items, such as stock-based compensation and depreciation.

General and administrative expenses consist primarily of personnel-rated expenses, including salaries, payroll tax, bonuses, and benefits, and professional services fees for legal, finance, and human resources, in addition to information technology expenses, rent expense, and other administrative functions, excluding non-cash expenses such as stock-based compensation and depreciation.

Other segment items consist primarily of interest income on cash and cash equivalents, partially offset by non-cash expenses, such as stock-based compensation and depreciation, and amortization of discounts and premiums on marketable securities.

12. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (29,655)	$ (23,584)	$ (85,459)	$ (61,278)
Net loss attributable to common stockholders, basic and diluted	$ (29,655)	$ (23,584)	$ (85,459)	$ (61,278)
Denominator:				
Weighted-average number of common stock used in net loss per share, basic and diluted	44,354,555	1,159,418	25,236,601	884,399
Net loss per share of common stock, basic and diluted	$ (0.67)	$ (20.34)	$ (3.39)	$ (69.29)

The Company's potentially dilutive securities, which include preferred stock, stock options, and warrants, have been excluded from the computation of diluted net loss per share as the effect is anti-dilutive since they would reduce basic net loss per share. Therefore, the weighted-average number of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following table summarizes the potentially dilutive common shares excluded from the computation of diluted net loss per share attributable to common stockholders:

	Nine Months Ended September 30,	
	2026	2025
Preferred stock	-	23,918,278
Stock options	6,799,641	2,791,229
Warrants	222,830	222,830
Total	7,022,471	26,932,337

13. Term Loan

In February 2026, the Company entered into a Loan and Security Agreement, or the LSA, with Banc of California, or the Lender, for the issuance of a term loan facility with an aggregate principal amount of up to $30.0 million, or the Term Loan. The Term Loan bears interest at an annual rate equal to the greater of the prime rate then in effect or 5%, payable monthly. The prime rate in effect as of September 30, 2026 was 7.00%. The maturity date of the Term Loan is June 30, 2030. In February 2026, the Company borrowed $15.0 million under the facility and the additional $15.0 million is available for drawdown through December 31, 2027.

In connection with the LSA, the Company granted the Lender a senior security interest in the Company's property and other assets, which has priority over any existing or future indebtedness and related security interests, subject to limited exceptions, including the Company's intellectual property. The LSA contains negative covenants that, among other things and subject to certain exceptions, could restrict the Company's ability to incur additional liens, incur additional indebtedness, sell or dispose of assets that constitute collateral, including certain intellectual property, and make payments of certain subordinated indebtedness. The LSA also contains certain events of default, including in the event of a material adverse change, and representations and warranties from the Company. Upon the occurrence of an event of default, the Lender may declare all outstanding obligations immediately due and payable, take such other actions as set forth in the LSA, and increase the interest rate otherwise applicable to the amount outstanding under the LSA by an additional 3.00%. The Company is in compliance with such covenants as of September 30, 2026.

The Company paid debt issuance costs of approximately $0.2 million in connection with the Term Loan. In addition, the Company issued a warrant to the Lender to purchase 22,500 shares of the Company's common stock with the exercise price of $9.81 per share. The Company estimated the fair value of the warrant to be approximately $8.08 per share using a Black-Scholes option pricing model. The warrant will expire ten years from the date of issuance. The fair value of the warrant at issuance was $0.2 million and was recorded in Stockholders' Deficit.

The issuance costs, which includes the amounts paid and the fair value of the warrant, that are directly attributable to the funded portion of the Term Loan have been presented as a direct deduction from the carrying value of the debt and are being amortized to interest expense over the term of the Term Loan using the effective interest method. Issuance costs attributable to the undrawn portion of the Term Loan of $0.2 million have been capitalized within other assets.

The Company issued 22,500 warrants in connection with the Term Loan at an exercise price of $9.81 per share. The fair value of the warrants issued in connection with the Term Loan was recorded to additional paid-in capital with an offsetting debt discount, which is amortized to interest expense over the term of the related debt.

On May 1, 2026, the Lender. submitted a notice of exercise for 22,500 warrants. Pursuant to the terms of the warrant agreement, the warrants were exercised on a cashless basis. In connection with the exercise, the Company issued 15,012 shares of common stock. The number of shares issued upon the cashless exercise was determined by dividing (i) the product of the number of warrants exercised multiplied by the excess of the fair market value of the Company's common stock over the aggregate exercise price by (ii) the fair market value of the Company's common stock. The fair market value used in the calculation was $29.49 per share, representing the closing price of the Company's common stock on April 30, 2026. No fractional shares were issued.

As of September 30, 2026, the carrying value of the Term Loan consisted of the following (in thousands):

Term loan	$	15,000
Debt discount, net of accretion		(183)
Term loan, net of discount	$	14,817

As of September 30, 2026, the $15.0 million borrowed under the Term Loan is recorded in non-current liabilities as no principal payments were due in the next 12 months. During the three and nine months ended September 30, 2026, the Company recorded $277.0 thousand and $647.0 thousand of interest expense related to the Term Loan, respectively, of which $16.0 thousand and $38.0 thousand were related to the amortization of the debt discounts, respectively.

Estimated future principal payments due under the Term Loan are as follows as of September 30, 2026 (in thousands):

Year ending December 31:	Term Loan Principal Payments
2026	$ —
2027	—
2028	6,000
2029	6,000
2030	3,000
Total principal payments	$ 15,000

14. Income Taxes

The Company did not record a provision or benefit for income taxes during the nine months ended September 30, 2026 and 2025. The Company continues to maintain a full valuation allowance against its U.S. federal and state deferred tax assets as it is more likely than not that such assets will not be realized in the future.

As of September 30, 2026 and December 31, 2025, the Company had no uncertain tax positions relevant to the jurisdictions where it is required to file income tax returns requiring recognition in the consolidated financial statements. As of September 30, 2026 and December 31, 2025, the Company had no accrued interest or penalties related to uncertain tax positions.

15. License Agreement

In April 2017, the Company entered into a license agreement, or the PARI License Agreement, with PARI Pharma GmbH, or PARI. Pursuant to the PARI License Agreement, PARI granted the Company an exclusive, sublicensable license to use its nebulizer devices for the development and commercialization of certain inhalant drug products as outlined in the PARI License Agreement. PARI additionally granted the Company a non-exclusive, sublicensable license to use certain proprietary accessories owned or controlled by PARI with the nebulizer devices for development of the drug products, as well as a non-sublicensable, exclusive sublicense to use certain Novartis patent rights which PARI licensed from Novartis for use with the nebulizer devices. PARI also granted the Company certain options to expand the licenses granted which would separately require amendments to the PARI License Agreement.

As consideration for the PARI License Agreement, the Company paid a non-refundable up-front initial payment of four hundred thousand EUR ($0.4 million). In addition, the Company agreed to make payments upon the achievement of certain developmental and regulatory milestones as it relates to its Drug Product, including initiation of Phase 2 and Phase 3 clinical trials, acceptance for filing by either the FDA or the European Medicines Agency, or the EMA, and approval by either the FDA or the EMA. Upon the achievement of these development and regulatory milestones, the Company is required to make payments up to, in aggregate, a low-mid single-digit million-euro amount for products using the device. The Company is additionally required to pay a mid six-figure-euro amount in the event that the Company consolidates or merges in a transaction in which 50% of the voting power of the Company is sold. After approval occurs, the Company is also required to pay PARI royalties equal to mid-single-digit percentage of net sales over a certain period. Further, following the first year of commercial sales in a major market, the Company shall pay a minimum annual royalty equal to a mid-single-digit percentage through the end of the relevant royalty term. Through September 30, 2026, the Company has met one developmental milestone, for which the payment was expensed to research and development when incurred. There were no regulatory milestones achieved during the nine months ended September 30, 2026 and 2025.

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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 in conjunction with our unaudited condensed consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report and our audited consolidated financial statements for the years ended December 31, 2025 and 2024, and related notes included in our final prospectus for our initial public offering, or the IPO, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on April 30, 2026, or the IPO Prospectus. References to the "Company," "Avalyn," "Avalyn Pharma" "we," "our," "us," or similar terms refer to Avalyn Pharma Inc. and its wholly owned subsidiaries, or either or all of them as the context may require. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions, and beliefs. The historical results are not necessarily indicative of results that may be expected in the future. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Special Note Regarding Forward-Looking Statements." Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage biopharmaceutical company on a mission to revolutionize the current treatment landscape for rare respiratory diseases, including progressive pulmonary fibrosis, or PPF, idiopathic pulmonary fibrosis, or IPF, and other interstitial lung diseases, or ILDs.

Our lead product candidate, AP01 (inhaled pirfenidone), is an optimized inhaled formulation of pirfenidone currently being evaluated in MIST, a global Phase 2b clinical trial in patients with PPF. AP01 has indicated encouraging tolerability and clinical activity in the ATLAS Phase 1b trial in patients with IPF and ongoing, multi-year SAIL open-label extension study in IPF and PPF patients, with long-term data supporting the potential to preserve lung function while improving tolerability relative to historical oral pirfenidone data. MIST is a randomized, double-blind, placebo-controlled trial evaluating two doses of AP01 in patients with PPF. This 52-week trial is designed to assess safety and efficacy of AP01, with a primary endpoint of change in lung function measured by forced vital capacity, or FVC. The study overenrolled, with a total of 398 patients randomized 2:1:2 into three treatment cohorts. Topline clinical data are anticipated in the second half of 2027.

Our second product candidate, AP02 (inhaled nintedanib), is an optimized inhaled formulation of nintedanib. We have completed a Phase 1 single-ascending dose, or SAD, trial in healthy volunteers and patients with IPF and a Phase 1 SAD and multiple-ascending dose, or MAD, trial in healthy volunteers. Results from these studies were published in September 2026 in *Respiratory Research.* AP02 is currently being evaluated in AURA, a global Phase 2 clinical trial in patients with IPF. Enrollment for the AURA trial was initiated in the first quarter of 2026 and is currently ongoing. AURA is a randomized, double-blind study evaluating two doses of AP02 dosed twice daily in patients with IPF. The 12-week study, which is designed to enroll 160 patients, will assess safety and efficacy as measured by FVC. Topline data are anticipated in late 2027.

We are also advancing AP03, an inhaled fixed-dose combination of pirfenidone and nintedanib, designed to deliver multiple antifibrotic mechanisms through a single lung-targeted platform, and have initiated a Phase 1 study of AP03 in healthy volunteers. The study has been cleared to proceed in Australia following Human Research Ethics Committee (HREC) and institutional approval, and notification to the Therapeutic Goods Administration under the Clinical Trial Notification (CTN) pathway. Results from the study are anticipated in the second half of 2027.

Since our inception in 2011, we have incurred significant operating losses and have not generated any revenue. On May 1, 2026, we completed our IPO, pursuant to which we issued and sold 19,166,667 shares of common stock, which included 2,500,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares. The aggregate net proceeds received by us from the IPO were approximately $316.6 million, after deducting underwriter discounts and commissions, as well as offering costs of $4.2 million. To date, we have funded our operations primarily with aggregate gross proceeds of $733.8 million from the sale and issuance of our common stock, preferred stock, and convertible notes, as well as from borrowing $15.0 million under our Term Loan, as defined above.

Due to our significant research, development, and manufacturing expenditures related to our clinical trials, we have accumulated substantial losses and negative cash flows since our inception, including net losses of $29.7 million and $23.6 million for the three

months ended September 30, 2026 and 2025, respectively, and net losses of $85.5 million and $61.3 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $350.8 million.

We expect our expenses and operating losses will increase substantially as we:

- continue to advance clinical development of our lead candidates, AP01 and AP02, and other current and future product candidates, including conducting our ongoing clinical trials;
- continue to advance our research activities and seek to discover, develop or acquire additional product candidates to expand our pipeline;
- pursue regulatory approvals for any current or future product candidates, including our lead PPF product candidate, that successfully complete clinical trials;
- continue to utilize third parties to manufacture our product candidates;
- continue to develop, maintain, expand, enforce, defend, and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our intellectual property portfolio;
- attract, hire, and retain additional qualified personnel;
- add operational, financial, and management information systems;
- undertake pre-commercial activities, and scale-up commercial infrastructure, including external commercial-scale manufacturing capabilities, to commercialize any current or future product candidates which may receive regulatory approval;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any current or future product candidates which may receive regulatory approval; and
- incur additional audit, legal, regulatory, tax, and other expenses associated with being a public company.

In addition, we have several clinical development, regulatory, and commercial milestones, as well as royalty payment obligations under the PARI License Agreement, as described below, and other agreements. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our ongoing and planned clinical trials and our expenditures on other research and development activities.

We do not have any products approved for sale and have not generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our current and any future product candidates, which we expect will take a number of years or may never occur. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings or other capital sources, potentially including collaborations, licenses, or other strategic arrangements. See the section titled "*—Liquidity and Capital Resources*." We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates, or grant third-party rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Due to the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or the timing of when, or if, we will be able to achieve or maintain profitability. Even if we generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2026, we had cash, cash equivalents, and marketable securities of $386.6 million. We believe, based on our current operating plans, that our cash, cash equivalents and investments in marketable securities will enable us to fund our operating expenses and capital expenditures into 2029. 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. See the sections titled "—Liquidity and Capital Resources" and "*Risk Factors—Risks Related to Our Financial Condition and Need for Additional Capital*" included elsewhere in this Quarterly Report.

Material Agreement

Below is a summary of the key terms for our material agreement.

PARI License Agreement

In April 2017, we entered into a license agreement, or the PARI License Agreement, with PARI Pharma GmbH, or PARI. Pursuant to the PARI License Agreement, PARI granted us an exclusive, sublicensable license to use its nebulizer devices for the development and commercialization of certain inhalant drug products as outlined in the PARI License Agreement. PARI additionally granted us a non-exclusive, sublicensable license to use certain proprietary accessories owned or controlled by PARI with the nebulizer devices for development of the drug products, as well as a non-sublicensable, exclusive sublicense to use certain Novartis patent rights which PARI licensed from Novartis for use with the nebulizer devices. PARI also granted us certain options to expand the licenses granted which would separately require amendments to the PARI License Agreement.

As consideration for the PARI License Agreement, we paid a non-refundable up-front initial payment of four hundred thousand EUR ($0.4 million). To date, we have met one developmental milestone, for which the payment of five hundred thousand EUR ($0.6 million) was expensed to research and development when the milestone was met. There were no regulatory milestones achieved during the year ended December 31, 2025, nor the nine months ended September 30, 2026.

Components of Results of Operations

Operating Expenses

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

Research and Development Expenses

Research and development expenses consist primarily of costs associated with the nonclinical and clinical development of our current and potential future product candidates. Our research and development expenses include direct costs specifically attributable to our programs including external expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, contract manufacturing organizations, or CMOs, consultants and our scientific advisors, and manufacturing expenditures, including costs for laboratory supplies, research materials and reagents, as well as indirect costs that are not directly attributable to a specific program such as:

- personnel-related costs, including salaries, payroll tax, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions; and
- facility costs, depreciation, and other expenses.

We recognize research and development costs in the periods in which they are incurred. Most of our research and development expenses have been related to identifying and developing our product candidates. Typically, external expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers as of each reporting date. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses, which are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered. Significant judgments and estimates are made in determining the accrued, or prepaid expense balances at the end of any reporting period.

External costs represent a significant portion of our research and development expenses, which we track on a program-by-program basis following the nomination of a product candidate. Our internal research and development expenses consist primarily of personnel-related expenses, including stock-based compensation expenses and allocated expenses. We do not track our internal research and development expenses on a program-by-program basis as they relate to costs that are deployed across multiple programs.

Product candidates in later stages of development generally have higher development costs than those in earlier stages resulting from larger and more complex clinical trials, manufacturing scale-up and an increase in research and development headcount to oversee these activities. As a result, management expects that our research and development expenses will increase substantially over the next several years as we potentially advance our product candidates into later-stages of development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, payroll tax, bonuses, benefits, and stock-based compensation charges for those individuals in executive, legal, finance, human resources, information technology, and other administrative functions. Other significant costs include professional service fees, including legal fees relating to intellectual property and corporate matters, and auditing, accounting, tax, and consulting services, as well as facilities and depreciation expense, and other general and administrative expenses that are allocated. We recognize general and administrative expenses in the periods in which they are incurred.

We anticipate that our general and administrative expenses will increase as we operate as a public company, which will require increased personnel costs, including salaries, benefits and stock-based compensation expenses, costs related to maintaining and protecting our intellectual property rights for our product candidates, expanded infrastructure, and higher legal, consulting and accounting services associated with maintaining compliance with the listing requirements of the Nasdaq Stock Market LLC and rules and regulations promulgated under the Exchange Act, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists primarily of interest earned and the amortization or accretion of discounts or premiums on our cash equivalents and investments in marketable securities.

Interest Expense

Interest expense consists of interest paid on our Term Loan, as well as non-cash interest expense for amortization of our debt discounts.

Other Income (Expense)

Other expense consists of realized and unrealized foreign currency gains and losses.

Income Taxes

Since our inception, we have not recorded any income tax benefits or expenses for the net losses we have incurred in each period or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards, or NOLs, and tax credits will not be realized. As of December 31, 2025, we had NOLs for federal and state income tax purposes of $190.3 million and $13.4 million, respectively. Of this amount, $9.9 million of the NOLs begin to expire in 2031, and the remainder are indefinite lived. The net state operating loss carryforwards will begin to expire in 2043. These loss carryforwards are available to reduce future federal taxable income, if any. As of December 31, 2025 and September 30, 2026, we have recorded a full valuation allowance against our net deferred tax assets.

Results of Operations

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

The following table summarizes our results of operations (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 25,491	$ 22,089	$ 3,402
General and administrative	7,603	3,234	4,369
Total operating expenses	33,094	25,323	7,771
Loss from operations	(33,094)	(25,323)	(7,771)
Other income	3,439	1,739	1,700
Net loss	$ (29,655)	$ (23,584)	$ (6,071)

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Direct research and development expenses by program:			
AP01	$ 11,964	$ 13,789	$ (1,825)
AP02	6,384	3,405	2,979
AP03	1,208	1,257	(49)
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	5,228	3,137	2,091
Facility and depreciation	203	91	112
Other research and development related costs	504	410	94
Total research and development expenses	$ 25,491	$ 22,089	$ 3,402

Research and development expenses increased by $3.4 million to $25.5 million for the three months ended September 30, 2026, from $22.1 million for the three months ended September 30, 2025. The increase in research and development expenses was primarily attributable to:

- $3.0 million increase of direct costs associated with our AP02 program costs driven by the progression of the Phase 2 clinical trial; and

- an increase in unallocated research and development expenses, primarily attributable to a $2.1 million increase in personnel-related expenses as a result of an increase in headcount as well as an increase in stock-based compensation resulting from stock options granted subsequent to the IPO, which was partially offset by a $1.8 million decrease of direct costs associated with our AP01 program costs driven primarily by the clinical trial approaching completion and patient participation winding down as subjects roll off the study.

General and Administrative Expenses

The following table summarizes our general and administrative expenses (in thousands):

	Three Months Ended September 30,		Change
	2026	2025	
Personnel-related (including stock-based compensation)	$ 4,275	$ 1,953	$ 2,322
Professional services & fees	2,674	1,013	1,661
Facility and depreciation	654	268	386
Total general and administrative expenses	$ 7,603	$ 3,234	$ 4,369

General and administrative expenses increased by $4.4 million to $7.6 million for the three months ended September 30, 2026, from $3.2 million for the three months ended September 30, 2025. The increase in general and administrative expenses was primarily attributable to:

- $2.3 million increase in personnel-related expenses, including stock-based compensation, driven by the increase of G&A headcount to support expanded research and development activities and overall corporate operations as well as an increase in stock-based compensation resulting from stock options granted subsequent to the IPO;
- $1.7 million increase in professional services and fees primarily driven by external legal and general and administrative consulting costs to support public company operations; and
- $0.4 million increase in facility expenses primarily associated with our office sublease entered into in September 2025 and the sublease expansion in June 2026.

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

The following table summarizes our results of operations (in thousands):

	Nine Months Ended September 30,		Change
	2026	2025	
Operating expenses:			
Research and development	$ 73,109	$ 55,290	$ 17,819
General and administrative	19,184	10,526	8,658
Total operating expenses	92,293	65,816	26,477
Loss from operations	(92,293)	(65,816)	(26,477)
Other income	6,834	4,538	2,296
Net loss	$ (85,459)	$ (61,278)	$ (24,181)

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Nine Months Ended September 30,		Change
	2026	2025	
Direct research and development expenses by program:			
AP01	$ 38,719	$ 37,248	$ 1,471
AP02	16,072	5,506	10,566
AP03	2,268	2,130	138
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	14,554	9,248	5,306
Facility and depreciation	417	273	144
Other research and development related costs	1,079	885	194
Total research and development expenses	$ 73,109	$ 55,290	$ 17,819

Research and development expenses increased by $17.8 million to $73.1 million for the nine months ended September 30, 2026, from $55.3 million for the nine months ended September 30, 2025. The increase in research and development expenses was primarily attributable to:

- $1.5 million increase of direct costs associated with our AP01 program costs driven by the progression of the Phase 2b clinical trial and ongoing open-label extension, or OLE, trial;
- $10.6 million increase of direct costs associated with our AP02 program costs driven by the progression of the Phase 2 clinical trial;
- $0.1 million increase of direct costs associated with our AP03 program, driven by scale-up activities; and
- an increase in unallocated research and development expenses, including stock-based compensation, primarily attributable to a $5.3 million increase in personnel-related expenses as a result of an increase in headcount as well as a significant increase in stock-based compensation resulting from stock options granted subsequent to the IPO.

General and Administrative Expenses

The following table summarizes our general and administrative expenses (in thousands):

	Nine Months Ended September 30,		Change
	2026	2025	
Personnel-related (including stock-based compensation)	$ 11,162	$ 6,302	$ 4,860
Professional services & fees	6,375	3,648	2,727
Facility and depreciation	1,647	576	1,071
Total general and administrative expenses	$ 19,184	$ 10,526	$ 8,658

General and administrative expenses increased by $8.7 million to $19.2 million for the nine months ended September 30, 2026, from $10.5 million for the nine months ended September 30, 2025. The increase in general and administrative expenses was primarily attributable to:

- $4.9 million increase in personnel-related expenses, including stock-based compensation, driven by the increase of G&A headcount to support expanded research and development activities and overall corporate operations as well as a significant increase in stock-based compensation resulting from stock options granted subsequent to the IPO;
- $2.7 million increase in professional services and fees primarily driven by general and administrative consulting costs to support public company operations; and
- $1.1 million increase in facility expenses associated with our office sublease entered into in September 2025 and the sublease expansion in June 2026.

Other Income

Other income increased by $1.7 million and $2.3 million for the three and nine months ended September 30, 2026, respectively, to $3.4 million from $1.7 million and $6.8 million from $4.5 million, respectively. The increase was primarily driven by interest income earned on the proceeds from the IPO, partially offset by the impact of lower federal funds rates.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates and any future product candidates. Further, we expect to continue to incur costs with operating as a public company. As such, we expect our research and development and general and administrative costs will continue to increase significantly.

To date, we have funded our operations primarily from proceeds from the sale of preferred stock, convertible notes, and common stock as a result of our IPO, as well as through proceeds received from our Term Loan. As of September 30, 2026, we had $386.6 million in cash, cash equivalents, and marketable securities. In February 2026, we entered into the LSA and the Term Loan, with the Lender for

the issuance of a term loan facility with an aggregate principal amount of up to $30.0 million. The interest rate on amounts borrowed will be equal to the greater of the prime rate then in effect, or 5.00%. The maturity date for the Term Loan is June 30, 2030. To date, $15.0 million has been borrowed under the Term Loan. In connection with the LSA, we issued warrants to the Lender to purchase 22,500 shares of our common stock. On May 1, 2026, we completed our IPO, pursuant to which we issued and sold 19,166,667 shares of common stock, resulting in net proceeds of approximately $316.6 million. To date, we have received aggregate gross proceeds of $733.8 million from the sale and issuance of our common stock, preferred stock, and convertible notes.

Future Funding Requirements

Due to the inherently unpredictable nature of nonclinical and clinical development and given the early stage of our programs and product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development of, obtain marketing approval for, and commercialize our products, if and when approved. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and nonclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which products, if approved, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We will need to raise substantial additional capital in the future.

Based upon our current operating plans, we believe that our existing cash, cash equivalents and investments in marketable securities, including the net proceeds from our IPO, will be sufficient to fund our operations into 2029. Our primary uses of capital are to fund research and development activities, compensation and related expenses, and general overhead costs. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current and future product candidates through discovery, nonclinical studies, and clinical trials.

Our future funding requirements will depend largely on:

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, nonclinical studies, and clinical trials of our current and future product candidates;
- the costs and timing of manufacturing for our current and future product candidates and commercial manufacturing;
- the costs, timing, and outcome of regulatory review of our current and future product candidates;
- the timing and amount of milestones, royalties, or other payments we may be required to make to third parties, including PARI, and the terms and timing of establishing and maintaining any other similar arrangements we may enter in the future;
- the legal costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- the costs associated with hiring additional personnel and consultants as our clinical activities increase and we start to scale up commercial infrastructure;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the financial terms of any agreement that we may enter into, including if we in-license or acquire additional product candidates or intellectual property; and
- costs of additional operational, financial, clinical, quality, legal, compliance and management information systems.

We have no committed sources of capital other than the $30.0 million under the Term Loan, $15.0 million of which has been drawn and up to $15.0 million remains available. Until such time, if ever, as we can generate substantial product revenue to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, potentially including collaborations, licenses, or other strategic arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. In addition, debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through a

strategic agreement, we may have to grant rights to develop and market our current and future product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

If we are unable to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts. See "*Risk Factors—We will need substantial additional funding. We may be unable to raise capital on acceptable terms, if at all, and, as a result, we may be required to delay, reduce, or eliminate our product development programs or commercialization efforts.*"

Cash Flows

The following table sets forth a summary of the net cash flow activity (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (82,237)	$ (57,283)
Net cash provided by (used in) investing activities	(155,456)	(38,891)
Net cash provided by financing activities	330,802	99,789
Net increase (decrease) in cash and cash equivalents	$ 93,109	$ 3,615

Operating Activities

For the nine months ended September 30, 2026, net cash used in operating activities was $82.2 million, which was primarily due to our net loss of $85.5 million and changes in our operating assets and liabilities of $3.1 million, offset by $6.3 million of non-cash charges related to stock-based compensation, depreciation, non-cash operating lease expense, and accretion of premiums on marketable securities.

For the nine months ended September 30, 2025, net cash used in operating activities was $57.3 million, which was primarily due to our net loss of $61.3 million, offset by changes in our operating assets and liabilities of $3.3 million and $0.7 million of non-cash charges related to stock-based compensation, depreciation, non-cash operating lease expense, and accretion of premiums on marketable securities.

Investing Activities

Net cash used in investing activities was $155.5 million for the nine months ended September 30, 2026, which was primarily driven by purchases of marketable securities and property and equipment of $241.0 million and $0.7 million, respectively, offset by sales and maturities of marketable securities of $86.2 million.

Net cash used in investing activities was $38.9 million for the nine months ended September 30, 2025, which was primarily driven by purchases of marketable securities and property and equipment of $109.3 million and $0.1 million, respectively, offset by maturities of marketable securities of $70.5 million.

Financing Activities

Net cash provided by financing activities was $330.8 million for the nine months ended September 30, 2026, which was primarily related to net proceeds of $316.6 million from the sale of common stock in the IPO and $14.8 million drawdown of the term loan facility, net of debt issuance costs, partially offset by $0.6 million of withholding tax payments in connection with the exercise of employee stock options.

Net cash provided by financing activities was $99.8 million for the nine months ended September 30, 2025, which was primarily related to the issuance of Series D convertible preferred stock of $99.8 million.

Contractual Obligations and Commitments

Other than as discussed below, there have been no material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations from our IPO Prospectus.

Term Loan

In February 2026, we entered into the Term Loan with Banc of California. $15.0 million has been borrowed under the Term Loan and the additional $15.0 million is available for drawdown through December 31, 2027. For more information on our Term Loan, refer to Note 13, Term Loan, in our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Leases

In September 2025, the Company relocated its headquarters to Boston, Massachusetts and entered into the Boston Sublease. Total fixed payments in connection with the Boston Sublease are $1.9 million over the term of the agreement ending in January 2029. In June 2026, we amended the Boston Sublease to expand the subleased premises, resulting in additional fixed payment obligations of $0.9 million over the remaining term of the agreement. This includes our share of facility operating expenses, real-estate taxes, but excludes our share of property management fees that are reimbursable to the sublandlord under the sublease.

Material Agreements

Our agreements with certain third parties to license intellectual property include potential milestone fees, sublicense fees, and royalty fees. The milestone fees are dependent upon the development of our drug products using the intellectual property licensed under the arrangements and contingent upon the achievement of development or regulatory approval milestones, as well as commercial milestones. These potential obligations are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty. For further information regarding these agreements, please see "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Material Agreement*."

Critical Accounting Estimates

The preparation of these financial statements in accordance with U.S. GAAP requires us to make judgments and estimates that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures during the reported periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For a description of critical accounting estimates used in the preparation of our consolidated financial statements, refer to our registration statement on Form S-1 for the year ended December 31, 2025. There have been no material changes to our critical accounting estimates.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited consolidated financial statements and unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means, among other things, the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies for so long as either (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this Quarterly Report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes included in the IPO Prospectus, before deciding whether to invest in our common stock. The risks described below are not the only ones facing us. The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment. This Quarterly Report also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial that also may impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Financial Condition and Need for Additional Capital

We are a clinical-stage biopharmaceutical company and have incurred significant operating losses since inception and anticipate that we will continue to incur significant operating losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company and have incurred operating losses in each year since our inception. Our net losses were $29.7 million and $23.6 million for the three months ended September 30, 2026 and 2025, respectively. Our net losses were $85.5 million and $61.3 million for the nine months ended September 30, 2026 and 2025, respectively. We had an accumulated deficit of $350.8 million and $265.4 million as of September 30, 2026 and December 31, 2025, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

Since our inception in 2011, we have devoted substantially all of our efforts and financial resources to the development of our product candidates, the continuation of ongoing clinical trials, the commencement of new clinical trials and ongoing manufacturing to support our product candidates. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet demonstrated an ability to conduct later-stage clinical trials, obtain regulatory approval, manufacture any product on a commercial scale or conduct sales and marketing activities necessary for successful product commercialization, and there is no assurance that we will accomplish any of these abilities in the future. Our operating history makes any assessment of our future success and viability subject to significant uncertainty. In addition, if we obtain marketing approval for any of our product candidates, we will incur significant sales, marketing, and manufacturing expenses. As a result, we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our operating losses may fluctuate significantly from quarter to quarter and from year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance clinical development of our lead candidates, AP01 (inhaled pirfenidone), or AP01, and AP02 (inhaled nintedanib), or AP02, and our other current and future product candidates, including conducting our ongoing clinical trials;
- continue to advance our research and nonclinical activities and seek to discover, develop additional product candidates;
- continue to utilize third parties to manufacture our product candidates and ensure sufficient supply of our manufacturing of drug substances, drug products and related medical devices;
- continue to develop, maintain, expand and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- attract, hire and retain additional qualified personnel;
- seek regulatory approvals for any current or future product candidates that successfully complete clinical trials;
- make any potential milestones, royalties or other payments due under any current or future in-license, collaboration or other agreements;

- undertake any pre-commercial activities and scale up external commercial-scale manufacturing capabilities;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval;
- add additional operational, financial, clinical, quality and management information systems; and
- incur additional audit, legal, regulatory, tax and other expenses with being a public company.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Given the numerous risks and uncertainties associated with pharmaceutical product development, it is not certain if any of our current or future product candidates will advance through late-stage development or be approved for commercial sale; therefore, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability.

Even if we successfully complete development and obtain the necessary regulatory approval for commercialization for any of our product candidates, we anticipate incurring significant costs associated with launching and commercializing such products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

We will need substantial additional funding. We may be unable to raise capital on acceptable terms, if at all, and, as a result, we may be required to delay, reduce, or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approvals and achieve product sales. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future as we initiate and conduct clinical trials of our current and future product candidates, scale-up and manufacture our product candidates, advance our nonclinical programs, seek marketing and regulatory approvals for any product candidates that successfully complete clinical trials and commercialize our products, if approved. Because the outcome of any clinical trial or nonclinical study is highly uncertain, we cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of any of our product candidates.

We believe that the net proceeds from our IPO, together with our existing cash, cash equivalents and marketable securities, inclusive of the $15.0 million borrowed under Term Loan, will be sufficient to fund our operating expenses and capital requirements into 2029. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including but not limited to changes in progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, complexity and results of discovery, nonclinical development and clinical trials for our current or future product candidates, including our ongoing clinical trials of our lead candidates, AP01 and AP02;
- the number of clinical trials required for regulatory approvals of our current or future product candidates;
- the extent to which we develop, in-license or acquire other product candidates in our pipeline;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through clinical development and, if approved, commercialization;
- the number and development requirements of product candidates that we may pursue;
- the timing and amount of the milestone, royalty or other payments we must make to PARI, pursuant to the PARI License Agreement, and any other third parties;
- the timing and amount of royalty payments we must make pursuant to the terms of a confidential settlement agreement;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any 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 rights and defending any intellectual property-related claims;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors (or patients' willingness to pay out-of-pocket for any approved products in the absence of such coverage) and adequate market share and revenue for any approved products;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval;
- the effect of macroeconomic trends including inflation, tariffs and interest rates;
- addressing any potential supply chain interruptions or delays, which may be due in part to international tariffs; and
- the costs of operating as a public company.

We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue implementing our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States, or the U.S., and worldwide resulting from factors that include but are not limited to, inflation, tariffs, global conflicts, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability and other factors. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and more dilutive. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy, or even cease operations.

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

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, such as grants, collaborations, licenses or other similar arrangements. We do not currently have any committed external source of funds other than the $30.0 million loan facility, $15.0 million of which has been borrowed as of September 30, 2026. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. Debt financing and preferred equity financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional funds through grants, collaborations, licenses or other similar arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams, intellectual property or product candidates, grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock or commit us to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, 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. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

The terms of our loan and security agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Our Loan and Security Agreement, or the LSA, with Banc of California provides us with up to $30.0 million of borrowing capacity, of which we have borrowed $15.0 million as of September 30, 2026. Our overall leverage, certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future

operations by limiting our ability to, among other things, satisfy our obligations under the LSA, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity. With certain exceptions, the LSA prohibits us from taking certain actions without Banc of California's prior consent, including, but not limited to any material transfers of our assets, changes in our business, management, directorship (in certain circumstances), ownership, or business locations; certain mergers or consolidations; incurring any indebtedness, other than permitted indebtedness; granting or permitting liens against our assets, other than permitted liens; making certain capitalized expenditures; entering into any material transaction with any affiliate, other than in the ordinary course of business; or making any payments in respect of any subordinated debt.

We intend to satisfy our current and future debt service obligations with our cash and cash equivalents and short-term investments and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. In the event of an acceleration of amounts due as a result of an event of default, we may not have sufficient funds and may be unable to arrange for additional financing to repay our indebtedness, and our lender could seek to enforce security interests in the collateral securing such indebtedness. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

Risks Related to the Discovery and Development of Our Product Candidates

We are substantially dependent on the success of our lead candidates, AP01 and AP02. If we are unable to advance such product candidates into later-stage clinical development or unable to obtain regulatory approval and commercialize a therapy for the treatment of pulmonary fibrosis, or PF, or experience significant delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates. We are substantially dependent on the success of at least one of our product candidates, including AP01, which is currently in Phase 2b clinical development for the treatment of PPF and AP02, which is currently in Phase 2 clinical development for the treatment of IPF.

The success of AP01, AP02, and our other current and any future product candidates will depend on several factors, including the following:

- successful and timely initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- the safety, tolerability and pharmacokinetic, or PK, profile of our product candidates observed in clinical trials;
- acceptance of regulatory submissions by the FDA and/or comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates;
- the frequency and severity of adverse safety findings in nonclinical studies and adverse events, or AEs, in clinical trials;
- timely and successful completion of nonclinical studies, including toxicology studies and in vitro dose projection studies in animals, where applicable;
- acceptance of our products, if approved, by PF patients, the medical community and third-party payors, and their perspective on the cost, safety, tolerability and efficacy and perceived advantages of alternative therapies for PF, including the current standard of care;
- maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of our product candidates and ability of such CROs and clinical sites to comply with clinical trial protocols, Good Clinical Practices, or GCPs, and other applicable requirements;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- receipt and maintenance of marketing approvals from applicable regulatory authorities for our initial target indication and label expansions to include new populations;
- maintaining relationships with our third-party manufacturers and their ability to comply with current good manufacturing practices, or cGMPs, as well as making arrangements with our third-party manufacturers for commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining, establishing, maintaining and enforcing patent and any potential trade secret protection or regulatory exclusivity for our product candidates;
- maintaining our arrangement with PARI pursuant to the PARI License Agreement for the exclusive license to PARI's eFlow® Technology and eRapid® Nebulizer System;
- maintaining an acceptable safety profile of our product candidates following regulatory approvals, if any;
- the sufficiency of our financial resources to fund our operations; and
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell our current or future product candidates.

If we are unable to develop, receive marketing approval for and successfully commercialize our product candidates, or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed.

We are early in our development efforts. If we are unable to successfully develop, receive regulatory approval for and commercialize any product candidate or successfully develop any other product candidate or experience significant delays in doing so, our business will be substantially harmed.

We are early in our development efforts. Each of our product candidates will require additional nonclinical and/or clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales.

Our assumptions about the development potential of AP01 and AP02 are based on the data generated from our clinical trials and from nonclinical studies. We may also observe materially and adversely different safety results as we continue to conduct our clinical trials.

Our product candidates will require substantial additional investment, clinical development, regulatory review, approval in one or more jurisdictions and significant marketing efforts before we could generate any revenue from product sales, if ever. Given our stage of development, it will take additional clinical development before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all.

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 our product candidates or any future product candidate we develop or if we experience delays in such approvals, we may not be able to continue our operations.

Further, conducting clinical trials in foreign countries, as we are currently doing, 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, failure to properly translate or interpret patient-reported outcome endpoints, managing additional administrative burdens associated with foreign regulatory schemes as well as political and economic risks relevant to such foreign countries.

The foregoing makes our ability to successfully and timely complete development of our product candidates and obtain regulatory approval for them less certain. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, our business, financial condition, results of operations and prospects could be materially harmed.

Additional time may be required to obtain marketing authorizations for product candidates that we develop as drug-device combination products.

Our nebulizer-delivered product candidates, AP01 and AP02, are subject to combination product development and approval regulatory requirements. Development of a product candidate as a combination product candidate requires close coordination with the

FDA and comparable foreign regulatory authorities for review of each of the drug and device components that comprise the product. Although the FDA and comparable foreign regulatory authorities have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

The regulatory approval processes of the FDA, European Medicines Agency, or EMA, and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain the required regulatory approval for any product candidate, our business will be substantially harmed.

We are not permitted to market, commercialize, sell, or promote any product candidate in the U.S. until we receive regulatory approval of a new drug application, or NDA, for such product candidate in a specific indication from the FDA. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates and any future product candidates in a timely manner. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations and 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. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future.

Prior to obtaining approval to commercialize any product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA, and other regulatory authorities. For example, certain of our trials did not include a placebo or an oral antifibrotic comparator arm, and interpretability of the findings and whether these findings are robust enough to warrant approval will be reviewed closely by the FDA, EMA, or other regulatory authorities. Such authorities may ultimately determine that our data are insufficient for approval and may require that we conduct additional clinical trials, or nonclinical or other studies, before our candidates can be approved. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs. For example, in July 2025, in our pre-IND discussions for AP02, the FDA, but no other regulatory agency, asked us to complete an additional device compatibility study (which we have since successfully completed) and also commented on a nonclinical rat toxicology study that showed findings that were considered non-adverse and/or species-specific. Due to this and our desire for a faster start-up time, we proceeded to initiate our Phase 2 clinical trial outside of the U.S. We intend to submit such IND with the safety and efficacy clinical data from our Phase 2 trial, if successful, to potentially enable a future Phase 3 clinical trial that includes U.S. sites. We believe that the data package including our Phase 2 trial, if successful, will provide compelling support to open an IND in the U.S. while enabling an efficient use of our resources.

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

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

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects. The FDA, EMA and comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. The U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays or changes. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any other regulatory authority.

Even if we complete clinical testing and receive approval of a NDA or foreign marketing application for our current or future product candidates, the FDA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, EMA or applicable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization, or failure to obtain our desired product label, would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue 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. Further, macroeconomic and other global conditions have impacted and could in the future impact the ability of the FDA, EMA and comparable foreign regulatory authorities to provide any required approvals or marketing authorizations for our product candidates or result in the delay of such approvals or authorizations.

Nonclinical and clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Our current assumptions about our product candidates' development potential are based on the data generated from nonclinical studies and clinical trials; however, we may observe materially and adversely different safety results as we continue to conduct our clinical trials. In order to obtain FDA, EMA or other comparable foreign regulatory authorities approval to market a new drug product, we must demonstrate the safety and efficacy of the drug in humans in a manner that satisfies the applicable authority's standards. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities, including the FDA, EMA and comparable foreign regulatory authorities, we must complete nonclinical development and then conduct extensive clinical trials to demonstrate the safety, potency and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of nonclinical testing and early clinical trials may not be predictive of the results of later clinical trials as to safety or efficacy, particularly if later clinical trials have a materially different trial design. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We have not completed all of the clinical trials required for the approval of any of our product candidates. We cannot assure you that any nonclinical study or clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates in the United States or in any other jurisdiction.

Additionally, we have in the past and intend in the future to utilize an "open-label" clinical trial design for certain of our clinical trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may

not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

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

We may incur additional costs and experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of nonclinical studies or clinical trials that could delay or prevent our ability to continue or complete clinical development, receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- experiencing delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates producing negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- failing to demonstrate statistical significance in clinical trials of our product candidates, which may impact the timing and design of late-stage clinical trials for such product candidates, or failing to demonstrate statistical significance in late-stage trials despite promising early stage results;
- the number of patients required for clinical trials of our product candidates being larger than we anticipate; enrollment in these clinical trials being slower than we anticipate, for example, due to the availability of standard of care therapy, changes to standard of care therapy, and the reluctance of patients to discontinue standard of care therapy in order to participate in certain of our future clinical trials; or participants dropping out of these clinical trials or failing to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates having undesirable side effects (including drug-drug interactions), unexpected toxicology findings, or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- future collaborators, if any, may conduct clinical trials in ways they view as advantageous to them but that are suboptimal to us;
- the cost of clinical trials of our product candidates being greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary, including comparator drug, to conduct clinical trials of our product candidates being insufficient, inadequate or too costly.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may, among other things:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval 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; or

- have the product removed from the market after obtaining marketing approval.

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

We have not yet completed all testing of any product candidate in clinical trials. Nonclinical, interim, topline, and preliminary results from our nonclinical studies or clinical trials are not necessarily predictive of the results or analyses of such results of later clinical trials. If we cannot replicate the positive results from any nonclinical studies or clinical trials of our current or potential future product candidates that have positive results, or if we suffer any other significant setbacks in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or potential future product candidates.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Nonclinical studies, Phase 1 and Phase 2a clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the side effects of product candidates at various doses and dosing schedules. Success in nonclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety, tolerability, PK profile, and efficacy in clinical development despite positive results in nonclinical studies or having successfully advanced through initial clinical trials, particularly because of our product candidates leveraging an inhalation approach.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical testing and earlier-stage clinical trials. Such setbacks have occurred and may occur for many reasons, including: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including post-treatment follow-up; our product candidates may fail to demonstrate effectiveness or safety in certain patient subpopulations or at all; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise. Data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development.

Similarly, from time to time, we may publish interim, topline, or preliminary results from our nonclinical studies and clinical trials, which are based on a preliminary analysis of then-available data. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, 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. Interim results 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. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline, and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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 investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Targeting PF with inhaled formulations of antifibrotic therapies is novel, and we do not know whether we will be able to successfully develop any inhaled products.

Our product candidates target PF with an inhaled formulation approach. Other companies have discontinued programs targeting PF as they were unable to develop compounds that could demonstrate safety or efficacy or whose dosing regimens were commercially unviable. Given our approach, we may not be able to successfully develop any products.

The PF market currently relies on oral systemic medications: nintedanib, pirfenidone, and nerandomilast. We aim to optimize inhaled formulations of the current oral antifibrotic medicines, as with AP01 and AP02, inhaled formulations of pirfenidone or nintedanib, for potentially improved safety and efficacy. While products for the treatment of PF have been approved by the FDA and comparable foreign regulatory authorities, to date, no inhaled antifibrotic therapy of pirfenidone or nintedanib, or combination of pirfenidone and nintedanib, has been approved, and to our knowledge, no product candidate combining these agents in an inhaled formulation is currently in clinical development. As a result, it is difficult to predict the developmental challenges we may encounter as our lead product candidates proceed through clinical trials, including our planned future clinical trials. It is also difficult for us to predict the time and cost of development, whether any of our clinical trials will be successful, whether any unexpected side effects that have not been associated with oral nintedanib and pirfenidone will be identified in our product development activities and whether our novel approach will result in the successful development and regulatory approval of any product candidates. For example, although we have not observed this to date in clinical trials, airway irritation is a potential risk for inhaled administration, which can be manifested by coughing, increased secretions, or bronchospasm. Any development problems we experience in the future related to our lead product candidates may cause significant delays or unanticipated costs, and such development problems may not be able to be solved. The novelty of our approach may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. For example, the FDA could require additional studies that may be difficult or impossible to perform, or prohibitively costly. Any of these factors may prevent us from completing clinical trials that we may initiate, and obtaining regulatory approval of or commercializing any product candidates we may develop, on a timely or profitable basis, if at all.

Our nonclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious or unacceptable adverse side effects or unexpected toxicology findings may be identified during the development of our product candidates, which could prevent or delay further clinical development, regulatory approvals and commercialization, impact the product's labeling, if approved, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. If our product candidates are associated with serious or significant adverse side effects in clinical trials or have adverse safety findings in nonclinical studies, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a benefit-risk perspective. The FDA, EMA or other comparable foreign regulatory authority or an institutional review board or ethics committee may also require that we suspend, discontinue or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. For example, in July 2025, in our pre-IND discussions for AP02, the FDA, but no other regulatory agency, asked us to complete an additional device compatibility study (which we have since successfully completed) and also commented on a nonclinical rat toxicology study that showed findings that were considered non-adverse and/or species-specific. Due to this and our desire for a faster start-up time, we proceeded to initiate our Phase 2 clinical trial outside of the U.S. We intend to submit such IND with the safety and efficacy clinical data from our Phase 2 trial, if successful, to potentially enable a future Phase 3 clinical trial that includes U.S. sites. We believe that the data package from our Phase 2 trial, if successful, will provide compelling support to open an IND in the U.S. while enabling an efficient use of our resources. If we are unable to obtain IND clearance from the FDA for AP02, our market opportunity may be adversely affected, and we may have to expend additional resources to complete additional nonclinical testing if required by the FDA. There is no guarantee that our efforts or further testing, if required, will be successful or will enable the clearance of an IND by the FDA.

Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause adverse side effects that prevented further development of the product candidate. For example, the long-term safety impacts of our product candidates are unknown and may not be discoverable in nonclinical studies or clinical trials that we may conduct. Additionally, if one or more of our product candidates receives marketing approval, and we or others subsequently identify undesirable side effects caused by such products a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product or seek an injunction against its manufacture or distribution;

- we may be required to recall a product;
- regulatory authorities may require additional warnings on the labels, such as a boxed warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related AEs to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We have obtained orphan designation for AP01 for the treatment of IPF and may in the future seek orphan drug designation for additional product candidates. Even if we obtain designation, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

In July 2014, we obtained orphan drug designation from the FDA for AP01 for the treatment of IPF. We may seek orphan drug designation or exclusivity in the indications targeted by our current or future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. For example, under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition. In order for the FDA to grant orphan drug exclusivity to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the U.S. or that affects 200,000 or more individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the U.S. Orphan drug designation must be requested before submitting an NDA. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet the required standard.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular drug for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated.

In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

A similar regulatory scheme governs approval of orphan product candidates by the EMA in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA (as applicable) from approving another marketing application for the same or another similar product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if at the end of the fifth year it is determined that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified.

While we may in the future seek designations for our product candidates with the FDA, EMA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or priority review, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA, EMA and comparable regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review of the marketing application(s). However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards of product quality, safety or efficacy required to be demonstrated in support of approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for one or more of our product candidates. If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Further, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure approval by the FDA. In addition, even if any product candidate we develop qualifies for Breakthrough Therapy Designation, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months from the FDA's acceptance of the application for review. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

We may not be able to submit investigational new drug, or IND, applications or IND amendments to commence 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 INDs, including the IND for our lead product candidates, on the timelines we expect. We may experience manufacturing delays or other delays with IND-enabling studies or it may require time to align with the FDA or comparable regulatory authorities on data packages. For example, in July 2025, in our pre-IND discussions for AP02, the FDA, but no other regulatory agency, asked us to complete an additional device compatibility study (which we have since successfully completed) and also commented on a nonclinical rat toxicology study that showed findings that were considered non-adverse and/or species-specific. Due to this and our desire for a faster start-up time, we proceeded to initiate our Phase 2 clinical trial outside of the U.S. We intend to submit such IND with the safety and efficacy clinical data from our Phase 2 trial, if successful, to potentially enable a future Phase 3 clinical trial that includes U.S. sites. We believe that the data package from our Phase 2 trial, if successful, will provide compelling support to open an IND in the U.S. while enabling an efficient use of our resources. If we are unable to obtain IND clearance from the FDA for AP02, our market opportunity may be adversely affected, and we may have to expend additional resources to complete additional testing if required by the FDA. There is no guarantee that our efforts or further testing, if required, will be successful or will enable the clearance of an IND by the FDA. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, 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.

We intend to deliver AP01 and AP02 and our other product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks.

We intend to deliver AP01 and AP02 and our other product candidates via a drug delivery device, a nebulizer, and there may be unforeseen technical complications related to the development activities required to bring such a product to market, including container compatibility and/or dose volume requirements. AP01 and AP02 and our other product candidates which may be delivered via drug delivery devices may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval.

We benefit from an exclusive license to PARI's eRapid® Nebulizer System with eFlow® Technology for AP01's delivery, and we retain an exclusive right to negotiate a separate license agreement with respect to AP02 and AP03 for exclusive licenses for PARI's eRapid® Nebulizer System with eFlow® Technology. This exclusivity offers a key competitive advantage, as the proprietary device would be included in any potential U.S. FDA-approved product labels, however, we cannot guarantee that we will maintain preferable commercial terms for such license. We are dependent on the sustained cooperation, effort and capability of PARI both to supply the device and, in some cases, to conduct the studies required for approval or other regulatory clearance of the device, and if received, we expect we will be dependent on PARI for continuing to maintain such approvals or clearances. Failure of PARI to supply the device, to successfully complete studies on the device or for any future devices we may utilize for any of our product candidates in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and delays in our product candidates reaching the market initially and/or expanding to new indications. For more information on the PARI License Agreement, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Material Agreement*."

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

As part of its decision to approve or grant marketing authorization for one or more of our product candidates, the FDA, European Commission, or EC, or other regulatory agencies may require us to perform certain post-marketing activities, such as completion of ongoing or planned studies, initiation of new studies or post-marketing clinical trials (including to assess safety risks), or additional analyses of existing data. Typically, we are required to provide annual updates on the progress of such required activities and to complete the activities by the assigned completion dates. Later discovery of previously unknown problems with our product candidates, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of such products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on or revisions to the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine, including under a risk evaluation and mitigation strategy, or REMS, program;
- fines, receipt of warning or untitled letters or suspension of clinical trials;
- refusal by the FDA, EC, or other regulatory agencies to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of marketing approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, the FDA, EC and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians may prescribe products for uses not described in the product's labeling, known as off-label uses, in their professional medical judgment, the FDA, EMA and comparable foreign regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products, if approved, in a manner inconsistent with their approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice and other comparable foreign regulatory agencies. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws, state consumer protection laws and laws of other comparable foreign regulatory agencies.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, and our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we identify and enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients with other trials. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. 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 as required by the FDA, EMA or comparable foreign regulatory authorities, or if a large number of patients withdraw.

For example, we are initially developing AP02 for the treatment of IPF, which is an orphan indication. In the United States, IPF is estimated to affect approximately 120,000 patients. As a result, we may encounter difficulties enrolling subjects in our clinical trials due, in part, to the small size of the patient population. If our target patient population is smaller than expected, we are unable to successfully enroll and retain patients in our clinical trials, or experience significant delays in doing so, we may not satisfy the FDA or other applicable regulatory authorities standards for number of patients enrolled due to enrollment being too low.

We cannot predict how successful we will be at enrolling subjects in future clinical trials. We may conduct clinical trials that would require patients to discontinue standard of care therapy, and we may experience challenges finding, enrolling and retaining PF patients in our planned clinical trials who are willing to discontinue their current treatment regimens to participate in our trials. Subject enrollment is affected by other factors including:

- the patient eligibility criteria as defined in the applicable protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the actual and perceived risks and benefits of the product candidate in the trial;
- effects of global health crises, such as those related to COVID-19, on enrollment and/or completion of a trial;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including the current standard of care and any new drugs that may be approved for PF, which may vary across the jurisdictions where we plan to conduct our clinical trials;
- the willingness of patients to be enrolled in our clinical trials;
- the success of efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain informed consent;
- the risk that patients enrolled in our clinical trials will drop out of the trials prior to completion;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the proximity and availability of clinical trial sites to prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

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. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or comparable foreign regulatory authorities to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

The results of clinical trials conducted at clinical trial sites outside the U.S. might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

We are currently conducting our Phase 2 clinical trials for AP01 and AP02 in Argentina, Australia, Canada, New Zealand, Turkey, the United Kingdom, and several European countries, and may conduct additional clinical trials outside of the U.S. in the future. Clinical trials conducted in Australia using "unapproved therapeutic goods," or those that have not yet been evaluated by the Therapeutic Goods Association, or TGA, for quality, safety and efficacy, must occur pursuant to either the Clinical Trial Notification Scheme or the Clinical Trial Approval Scheme. In each case, the trial is supervised by a Human Research Ethics Committee, or HREC, an independent review committee set up under the guidelines of the Australian National Health and Medical Research Council that reviews, approves and provides continuing oversight of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. Although the FDA, EMA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles such as institutional review board or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population and the data must be applicable to the U.S. population and U.S. medical practice in ways that

the FDA deems clinically meaningful. Further, the FDA may consider an on-site inspection to be necessary in which case they must be able to validate the data through such an inspection or other appropriate means. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the U.S. as adequate support of a marketing application. Similarly, any data submitted to foreign regulatory authorities may not adhere to their standards and requirements for clinical trials and data from trials conducted outside of such jurisdiction may not be accepted. Moreover, cultural and population differences across populations participating in trials conducted with sites outside the U.S. could introduce confounding factors that impact interpretation of the results from foreign clinical trial sites.

If the FDA, EMA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. In addition, such foreign trials would be subject to the applicable local laws and ethics committee requirements of the foreign jurisdictions where the trials are conducted, which may increase costs or time required to complete the clinical trial.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory and ethics committee requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and AEs;
- varying standards or availability of PF care, resulting in data that may differ from patients who have received the U.S. standard of care therapy;
- legislative proposals that, if enacted, could require additional fees or other compliance requirements for inclusion of foreign data in marketing applications;
- any pandemic, epidemic or public health emergencies;
- diminished protection of intellectual property in some countries; and
- political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations. Additionally, if any such third-party manufacturer cannot achieve compliance with import and export requirements or build a sufficient network of partners for the storage and distribution of our product candidates, our future global commercialization prospects could be materially harmed.

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

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered in an effort to optimize processes and product characteristics, and such optimization may not be achieved. Any of these changes could cause our product candidates to perform differently and affect the results of our current or future clinical trials. Such changes may also require additional testing, or notification to or approval by the FDA, EMA or another comparable regulatory authority. 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 commence sales and generate revenue.

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 management resources, we are initially focused on IPF and PPF, and we focus our research and development efforts on certain selected development programs and product candidates. We are currently primarily focused on the development of AP01, AP02 and AP03. As a result, we may forego or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. 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 development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We intend to develop AP03 as a fixed-dose combination of pirfenidone and nintedanib. Developing combination treatments increases complexity and risk, including risks of drug-drug interactions, unforeseen side effects or failures in our clinical trials that could delay or prevent their regulatory approval or limit the commercial profile of an approved label. Additionally, certain regulatory authorities may require a demonstration that each component makes a contribution to the claimed effects in addition to demonstrating that the combination is safe and effective for the intended population.

Under the FDA's combination rule, the FDA generally will not file or approve an NDA for a fixed-dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. If the FDA or other comparable foreign regulatory authorities require us to conduct one or more clinical trials to support such a demonstration, such as a factorial study, the design, duration, and scope of such clinical trials will be decided upon after further discussions with those agencies and other comparable foreign regulatory authorities. As a result, we are unable to predict with certainty the estimated timing or scope of any future clinical trials of AP03 we may be required to conduct to satisfy these requirements governing fixed dose combination products in various jurisdictions.

The development of AP03 as a combination of pirfenidone and nintedanib in an inhaled formulation may subject us to risks that we would not face if AP03 was being developed as a monotherapy. For example, combining pirfenidone and nintedanib with each other in oral formulation has not been feasible due to their additive side effect profiles. Combination of the two molecules in an inhaled formulation may result in adverse side effects or toxicities that pirfenidone and nintedanib do not produce when used alone (orally or in an inhaled formulation). In addition, pirfenidone and nintedanib may interact with each other in undesirable ways that could negatively impact the efficacy of AP03. Testing products in combination with each other may increase the risk of significant adverse effects or failed clinical trials.

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

We plan to seek FDA approval through the Section 505(b)(2) regulatory pathway for certain of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA for our product candidates to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We intend to rely on the Section 505(b)(2) pathway and FDA's prior determination of safety and efficacy for pirfenidone and nintedanib. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or if we are unable to successfully bridge our product candidates to approved pirfenidone and nintedanib products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding,

which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

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

Risks Related to Our Dependence on Third Parties

We are dependent on licensed intellectual property rights pursuant to the PARI License Agreement relating to the PARI eFlow® Technology and eRapid® Nebulizer System and we may in the future enter into additional intellectual property licensing agreements on which we could similarly become dependent. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved, on the intended timeline. If we breach the PARI License Agreement or any other future agreements in which we license the use, development and commercialization rights to our product candidates from third parties or, in certain cases, we fail to meet certain deadlines, we could lose license rights that are important to our business.

We are a party to the PARI License Agreement under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future with PARI or other third parties. Pursuant to the PARI License Agreement, we have secured an exclusive license to develop and commercialize our inhaled candidates with PARI's eFlow® Technology and eRapid® Nebulizer System. The PARI License Agreement imposes, and we expect that future license agreements will 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 such agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Material Agreement*" for additional information on the PARI License Agreement.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement intellectual property. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

In some circumstances, we may not have the right to control the maintenance, prosecution, preparation, filing, enforcement, defense or litigation of patents and patent applications that we license from or license to third parties and may be reliant on our licensors or licensees to do so. We thus cannot be certain that activities such as patent maintenance and prosecution by our licensors have been or will be conducted consistent with our best interests or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If our licensors fail to maintain such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any product candidates that are the subject of such licensed rights and our right to exclude third parties from commercializing competing products could be adversely affected.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our product candidates.

Furthermore, if our licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, certain of these license agreements, may not be assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions.

The PARI License Agreement is, and future license agreements that we enter into are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently rely on, and in the future intend to rely on, third parties to conduct a significant portion of our clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We currently engage CROs and other vendors to conduct our ongoing clinical trials, including our ongoing Phase 2 clinical trials of AP01 and AP02, and similarly expect to engage CROs and other vendors for future clinical trials for these and other product candidates that we may progress to clinical development, including the planned Phase 1 clinical trial of AP03. We expect to continue to rely on third parties, including but not limited to clinical data management organizations, healthcare institutions operating as clinical sites and clinical investigators, to conduct those clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties

terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs or other vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or vendor commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. We may encounter challenges or delays in our CRO/vendor relationships in the future which may cause a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our clinical trials will not be our employees, and, except for including contractual obligations and remedies for breach of such obligations in our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our 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 approvals for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

We rely on these parties for execution of our nonclinical studies and clinical trials, and generally do not directly control their businesses or related activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register certain ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, 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. Further, upon inspection by a given regulatory authority, such regulatory authority may not agree with our determination that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We contract with third parties for the manufacture of our product candidates for clinical drug and device supply and expect to continue to do so for commercialization, if our product candidates are approved. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any cGMP manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We currently rely, and expect to continue to rely, on contract development and manufacturing organizations, or CDMOs, for the cGMP manufacture of our product candidates and related raw materials for clinical development. In addition, we expect to rely on CDMOs for the commercial supply of any products for which we receive marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, any of these third parties may terminate their engagements with us at any time or may face production shortages or other supply interruptions or otherwise be unable to secure the requisite raw materials to support our planned clinical activities. In addition, the availability of CDMOs to manufacture our product candidates/drugs may depend in part on the CDMOs' schedules for manufacturing other companies' products or product candidates. If we need to modify our development plans or enter into alternative arrangements, which may not be readily available or available on acceptable terms, it could delay our product development activities and increase our expenses.

Our reliance on CDMOs for manufacturing activities will reduce our control over these activities, but will not relieve us of our responsibility to ensure compliance with all required regulations. In particular, we do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may be unable to obtain regulatory approval of our potential future marketing applications. In addition, although we conduct routine qualification audits and have quality agreements in place with our CDMOs, we have no direct operational control over their ability to maintain adequate quality control, quality assurance and qualified personnel. Our CDMOs may face manufacturing or quality control problems causing production and shipment delays, or CDMOs may fail to maintain compliance with the applicable cGMP requirements. The facilities used by our CDMOs are subject to continual review and periodic inspections by the FDA and comparable foreign regulatory authorities. If the FDA or a comparable foreign regulatory authority finds deficiencies with or 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 regulatory 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 clinical holds, 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 supply of our products.

Our use of foreign CROs and CDMOs in some jurisdictions may be or may become subject to U.S. legislation, including sanctions, trade restrictions and other regulatory requirements, which may increase the cost of and cause delays in the procurement or supply of materials for, or manufacture of, our product candidates or have an adverse effect on our ability to secure significant commitments from governments to purchase its potential therapies.

Moreover, we rely on sole suppliers for certain steps in the manufacturing supply chain of pirfenidone and nintedanib. If these sole suppliers are unable to supply to us in the quantities we require, or at all, or otherwise defaults on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long-term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current CDMOs cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement. In addition, our current and anticipated dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may seek to establish collaborations, license agreements and other similar arrangements with third parties for the development or commercialization of our product candidates. If we are not able to establish them on commercially reasonable terms, or if those arrangements are not successful, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional funding. For some of our product candidates, we may seek to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the U.S. If we enter into any such additional arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

We face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for any 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 potential differentiation of our product candidate from competing product candidates, the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, and industry and market conditions generally. The collaborator may also consider alternative product

candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected, or at all;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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 the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated, including for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and
- we may be required to invest resources and attention into such collaboration, which could distract from other business objectives.

We may not be able to negotiate future 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 any product candidate that we planned to collaborate on, 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 revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, any future collaborations that we enter into may not be successful. The success of our future collaboration arrangements will depend heavily on the efforts and activities of our future collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. If conflicts arise between any future collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. For example, our future collaborators could conduct multiple product development efforts and could develop, either alone or with others,

products in related fields that are competitive with the product candidates we may develop. In addition, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party, and any such termination or expiration may adversely affect us financially or harm our business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating, or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we own issued patents, our pending and future patent applications, may not result in issued patents. Even if our owned or licensed patent applications result in issued patents, we cannot assure you that such issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties, or that they will effectively prevent others from commercializing competing technologies, products, or product candidates.

Obtaining and enforcing patents is expensive, complex, and time-consuming, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our owned or licensed patent applications at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we may have the right to have some input in connection with such activities, we may not have the right to control the preparation, filing, and prosecution of patent applications that are licensed to us by third parties, or to control prosecution and maintenance of patents that we out-license to third parties. For example, we do not control the prosecution or enforcement of certain intellectual property licensed from PARI. Therefore, patents and applications that are relevant to our product candidates may not be prosecuted and enforced in a manner consistent with the best interests of our business. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates.

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 provide protection without regard to any method of use. Similarly, patents for pharmaceutical formulations containing pharmaceutical product candidates may provide an additional form of intellectual property protection, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to the pharmaceutical formulations of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that such claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. In addition, we cannot be certain that the claims of such patents, and applications if granted, will be sufficiently broad to effectively prevent competitors from working around our claimed inventions by developing an alternative formulation and thereby competing with us without infringing our patent rights. Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside methods of use included in our owned or licensed patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their product for indications that are covered by our owned or licensed patents, clinicians may prescribe these competitor products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

The issued patents we own or license that cover our pharmaceutical product candidates may expire at such a date that such patents may not prevent competitors from developing, making and marketing a product that is identical to our product candidates after expiration of any applicable regulatory exclusivities.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability, and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued that protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our owned patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our owned or licensed patents and pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our owned or licensed pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO, and our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, interferences, *inter partes* review proceedings, or other similar proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

A third party may also claim that our owned patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products, or product candidates without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations, and prospects.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, and trade secret protection to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any future partners, collaborators, licensors or licensees, 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 of form in the preparation or filing of our owned or 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 partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future partners, collaborators, licensees or 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 owned or 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.

We anticipate additional patent applications will be filed both in the United States and in other countries, as appropriate. However, we cannot predict:

- if additional patent applications covering new technologies related to our product candidates will be filed;
- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our owned or licensed patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether any of our owned or licensed patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our owned or licensed patents and patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending and future patent applications covering 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 or patentable by courts in the United States or foreign countries.

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

Patents are of national or regional effect. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In some cases, we or our licensors may not be able to obtain patent protection for certain technology outside the United States. Competitors may use our technologies in jurisdictions where we and our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our owned or licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our owned or licensed patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our 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 owned or licensed patents at risk of being invalidated or interpreted narrowly and our owned or licensed 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 licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Various countries outside the United States 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. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or any of our licensors is 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

Third-party claims of intellectual property infringement, misappropriation, or other violation may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability and the ability of our future collaborators to develop, manufacture, market, and sell our product candidates without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated to our products or activities, which block our efforts or may potentially result in our product candidates or our activities infringing such claims.

There is a substantial amount of litigation involving the infringement of patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe, misappropriate, or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our owned or licensed patent portfolio may therefore have no deterrent effect. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods.

If a third party alleges that we infringe, misappropriate, or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees, and other amounts, and/or grant cross-licenses to intellectual property rights protecting our products; and
- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

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

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting nonclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If a product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that third-party patents are valid, enforceable, and infringed, which could adversely affect our ability to commercialize our product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent or find that our product candidates or technology did not infringe any such claims.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our owned or licensed patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe, misappropriate, or violate our owned or licensed patents, trademarks, or other intellectual property. To counter infringement, misappropriation, or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert

counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our owned or licensed patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competing products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

If we file a Section 505(b)(2) application that references a product marketed by another manufacturer, we may be subject to a patent infringement suit and the approval of our product may be delayed.

If we file a Section 505(b)(2) application that relies in whole or in part on studies conducted by a third-party, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to the third-party NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our drug. A certification that our new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our Section 505(b)(2) application is accepted for filing by the FDA. The third-party may then initiate a lawsuit to defend the patents identified in the notice and sue us for infringing such patents. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the Section 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of us. The third-party may file a patent infringement lawsuit against us outside the 45-day period, in which case, our Section 505(b)(2) application will not be subject to the 30-month stay of FDA approval. If we are sued for patent infringement by a third party and are unsuccessful in defending such suit, we may be prevented from commercializing our product unless we are able to obtain a license from such third party, which may not be available on commercially reasonable terms or at all, and the occurrence of such event could have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our current or future licensors initiates legal proceedings against a third party to enforce a patent covering our product candidates, or our other proprietary technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution.

In addition to such counterclaims, third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights in such a way that they no longer cover our product candidates, and any other proprietary or platform technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection provided to our product candidates, or other components of our programs, as applicable. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications.

No assurance can be given that, if challenged, our owned or licensed patents would be declared by a court or an administrative body to be valid or enforceable.

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

Our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining, and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents and future issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and 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 post-grant review, *inter partes* review, and derivation proceedings.

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

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. Consequently, if a third party files a patent application in the USPTO before we file an application covering the same invention, the third party could 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 will require us to be cognizant going forward of the time from invention to filing of a patent application. 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 (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) 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 and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents and future issued patents, all of which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to enforce patents or obtain new patents. We cannot predict how future decisions by the courts, the United States Congress, or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations, and prospects.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a unitary patent system took effect on June 1, 2023. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. 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 resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that our future licensors are not the sole and exclusive owners of the patents we may in-licensed. If other third parties have ownership rights or other rights to our future 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 adversely affect our competitive position, business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Individuals executing agreements with us may have preexisting or competing obligations to a third party and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. 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 adversely affect our business, financial condition, results of operations, and prospects.

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

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate, or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations 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.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain United States applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates, or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents may result in revived patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidates or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidates.

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 product candidates 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 product candidates.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our product candidates, their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Patent terms may be inadequate to protect our competitive position on products or product candidates for a sufficient 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 United States non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competing products, including generics. Given the amount of time required for the development, testing, and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and patent applications. We rely on our outside counsel, or third party vendors, to pay these fees due to United States and non-United States patent agencies. The USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on PARI to take the necessary action to comply with these requirements with respect to the intellectual property licensed under the PARI License Agreement and may be similarly dependent on licensors in the future. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations, and prospects.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed, whether inadvertently or through intentional acts of current or departing employees, or that competitors will not otherwise gain access to our trade secrets. If any of the employees, consultants or advisors who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. 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. 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; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach. If our trade secrets are not adequately protected, our business, financial condition, results of operations, and prospects could be adversely affected.

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our 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. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties 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 registered 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects.

We may be subject to claims asserting that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants, or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. 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. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants, or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to ours, but that are not covered by the claims of the patents that we license or may own in the future;
- if and when patents will issue;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to now or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis;
- 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;
- the patents or other intellectual property rights of others may have an adverse effect on our business; or
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Legal and Regulatory Compliance Matters

Our business operations and our relationships with healthcare providers, third-party payors, patients and other parties in the healthcare industry are subject, directly or indirectly, to significant regulation under a broad range of healthcare laws, including fraud and abuse laws. Any action against us for violation of such laws could harm our reputation and require significant resources for defense. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Pharmaceutical manufacturers, and the parties with which such manufacturers interact, are subject to extensive and complex regulation under a broad range of healthcare laws. Such laws, some of which will apply only if and when we have a marketed product, constrain our business operations, including the research and development, manufacturing, distribution, sales and promotion of our product candidates and products, if any are approved in the future, as well as educational and charitable activities. Arrangements with healthcare provider, third-party payors, patients and other parties in the healthcare industry professionals, which may have a significant impact on our business, are regulated by fraud and abuse and other healthcare laws. For more information, see the section titled "*Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements*" included in our IPO Prospectus.

Healthcare laws regulating our business activities are broad and any exceptions may be narrow. Requirements may differ across jurisdictions. There may be limited guidance on the interpretation of the laws and their application to our specific activities. Interpretations of these laws by government enforcement agencies and courts are evolving. Efforts to ensure that our business operations will comply with applicable healthcare laws and regulations will involve substantial costs. We will need to develop and implement robust compliance policies and processes to seek to prevent and detect non-compliance and update such policies and processes as our operations and government expectations evolve, which will involve substantial and ongoing costs, and even with such policies and processes we cannot be certain to prevent non-compliance.

Given the broad scope, limited guidance and evolving government interpretations, our business activities may nonetheless potentially be subject to challenge under these healthcare laws despite efforts to ensure compliance. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Such an action could also harm our reputation and adversely affect our business as a result. 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, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm, and the curtailment or restructuring of our operations, any of which could harm our business.

Even if we obtain regulatory approvals for our product candidates or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approvals for our product candidates or any future product candidates, such product candidates, once approved, will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and post-marketing activities, among other things. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic and unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. Any regulatory approvals that we receive for our product candidates or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing, including additional trials and heightened surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to promptly report any serious and unexpected adverse drug experiences and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to ensure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA, EMA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies, including their sales force, with respect to off-label uses of products for which marketing approval has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of annual fees and continual review and periodic inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with any product, if approved, such as adverse experiences of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting revisions to the approved labeling to add new safety information, imposing of post-market studies or clinical trials to assess new safety risks or imposing distribution restrictions or other restrictions under a REMS program, requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines, disgorgement or profits or revenue, warning letters or adverse publicity requirements;
- suspend or withdraw regulatory approvals;

- restrict product distribution or use, including full or partial holds on any ongoing or planned clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

Healthcare and other reform initiatives may have an adverse impact on our business and results of operations.

In the U.S. and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of any product candidates that we may develop; restrict or regulate post-approval activities; and affect our ability to profitably sell any product candidates for which we obtain marketing approval. These reform efforts may result in more rigorous coverage criteria, additional downward pressure on the price that we, or our future collaborators, may receive for any approved products, or in other consequences that may adversely affect our ability to achieve or maintain profitability. For more information, see the section titled "*Business—Government Regulation—Healthcare Reform*" included in our IPO Prospectus.

There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results. The implementation of healthcare reform measures, including drug price negotiation programs, pricing transparency requirements, and state-level pricing controls, could significantly reduce the prices we are able to charge for any approved products, limit our commercial opportunities, or impose substantial compliance costs. We may be required to provide significant discounts or rebates, participate in government price negotiation programs on unfavorable terms, or face restrictions on product access that limit our ability to commercialize our products successfully. Additionally, implementation by third party payors of policies and practices to limit coverage, manage utilization, reduce payment of drug products could adversely affect our ability to sell our products profitably. The effect of these pricing pressures and access restrictions may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Further, we cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action, which could impose additional restrictions or costs on our business that we have not anticipated.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, for example, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our ability to obtain adequate reimbursement for any approved products and on our results of operations.

Risks Related to the Commercialization of Our Product Candidates

We face substantial competition and we may not be able to compete successfully in this environment.

We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, or that we are unable to compete with existing entities that have made substantial investment into novel treatments for disease, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop. The development and commercialization of new drug products is highly competitive. We will face competition with respect to our product candidates and any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent or other intellectual property protection and establish collaborative arrangements for research, development, manufacturing and commercialization. There are larger

pharmaceuticals that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, while others are based on entirely different approaches. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for any product candidates we may develop.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, conducting nonclinical studies and clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates 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. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent or other intellectual property rights, we could face risks relating to our ability to successfully prevent or delay launch of competitors' products. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidates that we may develop and commercialize. The biotechnology and pharmaceutical industries are characterized by rapid advances, intense competition and a strong emphasis on proprietary and novel products and product candidates. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, consortiums and public and private research institutions.

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

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. There is currently a well-established oral standard of care for PF: pirfenidone (ESBRIET®, marketed by Legacy Pharma Inc. in the U.S. and Genentech/Roche globally), nintedanib (OFEV®, marketed by Boehringer Ingelheim), and nerandomilast (JASCAYD®, initially marketed by Boehringer Ingelheim) with which physicians, PF patients and payors are very familiar and for which an established benefit-risk profile exists. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing the current standard of care if we are unable to demonstrate competitive efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant or unwilling to take their patients off their current medication, and switch their treatment regimen to our product candidates or add-on our product to their treatment regimen, if approved, if the current medication is effective. Further, patients often acclimate to the treatment regimen that they are currently taking and may not want to switch or add-on unless recommended to do so by their physician for clinical reasons or required to do so due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA, EMA and other regulators and receive approval, concerns in the medical community related to the comparative efficacy or side effect profile of our products may hinder market acceptance and uptake.

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

- the efficacy, safety and potential advantages compared to alternative treatments;
- whether a product candidate is approved, if ever, as an add-on to standard of care or as part of a proprietary combination therapy;

- the prevalence and severity of any side effects;
- our ability to offer our products at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any boxed warning;
- the product's acceptance into current standard of care treatment algorithms by medical societies that could affect payor and physician uptake;
- the impact of the combination of our product candidates with a drug delivery device on cost of treatment with our products or the convenience for patients, if approved;
- the effectiveness of sales and marketing efforts, and the strength of sales, marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for any product candidates, once approved;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- any restrictions on the use of our products together with other medications; and
- potential product liability claims and unfavorable publicity related to our products.

Any failure by one or more of our product candidates that obtains regulatory approvals to achieve market acceptance or commercial success would adversely affect our business prospects.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of either lead product candidate, or any of our other current or future product candidates, or misread trends in the pharmaceutical industry, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We owe royalty payments to a third party pursuant to the terms of a confidential settlement agreement.

Pursuant to the terms of a confidential settlement agreement, for a period beginning upon first commercial sale and ending on the later of the expiration of the last to expire patent right or twenty years after such first commercial sale, we are obligated to pay a third party royalties in the amount of 0.25% of net sales on any pirfenidone product, including AP01, and 0.5% of net sales of any nintedanib product, including AP02, although the agreement specifically excludes any percentage of net sales on AP03 as a combination product. The payment of the royalties will impact our future revenue and may make it more difficult to engage in collaborations, licenses or the acquisition of certain product candidates, and may result in us ceasing to develop certain product candidates or all of our product candidates if we determine that it will not be financially profitable to do so.

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

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate 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 may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

The success of our product candidates or any future product candidate will depend significantly on coverage and adequate reimbursement by third party payors or the willingness of patients to pay for these products if not covered.

We believe that for any product candidates which may be approved, our success depends on obtaining and maintaining coverage and adequate reimbursement for such products for their respective approved indications, and the extent to which patients will be willing to pay out-of-pocket for such products in the absence of reimbursement for all or part of the cost. Accordingly, we will need to establish a coverage and reimbursement strategy for any approved product candidate. In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government and private third-party payors decide which products they will cover and establish reimbursement levels. Coverage and reimbursement varies among third party payors and new products face significant challenges in obtaining and maintaining coverage and adequate reimbursement, particularly if approved for indications with established treatments already on the market. For more information, see the section titled "*Business—Government Regulation—Coverage and Reimbursement*" included in our IPO Prospectus.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage for certain products, managing utilization of covered products and restricting the amount of reimbursement for covered products. Within the U.S., net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or requested by private payors in exchange for favorable coverage. The process of obtaining coverage and reimbursement determinations from third-party payors can be lengthy, unpredictable, and costly, with no guarantee of success. Even if we obtain favorable coverage decisions, payors may subsequently revise their policies in ways that adversely affect our products. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. For more information, see the section titled "*Business—Government Regulation—Healthcare Reform*" included in our IPO Prospectus.

There can be no assurance that our product candidates, even if they are approved for sale in the U.S. or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

The market for our product candidates may be smaller than we estimate.

Our estimates of the potential market opportunity for our product candidates include several key assumptions, based on our industry knowledge, industry publications and third-party research reports. These assumptions include the number of patients who have PF, as well as the estimated reimbursement levels for each product candidate, if approved. While we believe our assumptions and the data underlying our estimates are reasonable, and believe that the assumptions and data underlying the estimates of third-party led market

research are similarly reasonable and accurate, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. Further, new studies may change the estimated incidence or prevalence of these diseases, and the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. If the actual market for any product candidates we may develop is smaller than we estimate, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Clinical trial and product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop, especially if our products are prescribed for off-label uses (even if we do not promote such uses). For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale.

Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we maintain clinical trial liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval on any current or potential product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Each of our executive officers and employees may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approvals of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Further, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2026, we had 56 full-time employees, including 36 who were engaged in research and development activities. As we continue to build our organization and execute on our strategy, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management, business, and development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage our growth effectively.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate and plan to operate in a highly regulated industry and we could now or in the future be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage, and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources and cause reputational harm.

Inadequate funding for the FDA, the Securities and Exchange Commission and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise

prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

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

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

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA or other comparable regulatory authority regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or other comparable regulatory authority, manufacturing standards, foreign, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud and abuse, such as the payment of kickbacks in return for business. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use or misrepresentation of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any of these could adversely affect our ability to operate our business and our results of operations.

If our third-party manufacturers or suppliers do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.

We and any CDMOs and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Manufacturing operations for our product candidates involve the use of hazardous and flammable materials, including chemicals and biological materials. These operations also produce hazardous waste products. We or the manufacturers we contract with 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 the use of hazardous materials by us or by one of our third party-manufacturers, we could be held liable for any resulting damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. We and our

third-party manufacturers and suppliers cannot eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we and our third-party manufacturers and suppliers may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which may increase the cost of their services to us. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities for us or our third-party manufacturers and suppliers, or adversely impact our supply chain or reputation, which could in turn materially adversely affect our business, financial condition, results of operations and prospects.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment directors' and officers' and employment practices insurance, however, we may not be able to maintain adequate levels of insurance coverage in the future. Further, an insurance carrier may seek to cancel or deny coverage after a claim has occurred.

We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses, present significant distractions to our management and harm our financial condition and results of operations.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and strategic partnerships or out-licensing or in-licensing of intellectual property, product candidates or products. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any licensed assets that we may acquire rights to in the future may disrupt our existing business, may cause delays related to the integration of any licensed or acquired assets, and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to our entry into any licensing or partnerships, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Our operations and the operations of our suppliers, CROs, CDMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards, and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely or expect to rely on third-party manufacturers or suppliers to produce our product candidates and their components and on CROs and clinical sites to conduct our clinical trials, and do not currently have a redundant source of supply for all components of our product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of our product candidates or any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to Ownership of Our Common Stock

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

An active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, the value of our shares may be impaired, and it may be difficult for our stockholders to sell shares at an attractive price or at all. An inactive market may also impair our ability to raise capital by selling shares, which in turn could materially adversely affect our business.

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates or any other change in the competitive landscape of our industry;
- our ability to successfully recruit and retain subjects for clinical trials and any delays caused by difficulties in such efforts;
- the timing and cost of, and level of investment in, research, development, regulatory approvals and commercialization activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates;
- the level of demand and the indication for any approved products, which may vary significantly;
- the risk/benefit profile, cost, coverage, and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other agreements; and
- general market and economic conditions, including market conditions in the pharmaceutical and biotechnology sectors.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated revenue or earnings guidance.

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

The market price for our stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. These factors include:

- the commencement, enrollment or results of our current or future clinical trials of our product candidates;

- adverse results from, delays in, suspension or termination of current or future clinical trials or nonclinical studies of our product candidates, or any delay in advancing a clinical candidate;
- the success of competitive products gaining approvals or announcements by current and future competitors of their product development efforts;
- any delay in our regulatory filings for our product candidates or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse regulatory decisions, including the failure to authorize or approve the conduct of one or more clinical trials of our product candidates, the failure to receive regulatory approvals of our product candidates, or the failure of a regulatory authority to accept data from clinical trials conducted in other countries;
- the reporting of unfavorable nonclinical or clinical results;
- our success or failure to identify, develop, acquire or license additional product candidates;
- the degree and rate of physician and market adoption of any of our current and future product candidates, if successfully developed and approved;
- manufacturing, supply or distribution delays or shortages, including our inability to obtain adequate supply of drug product, drug substance, raw materials or any commercially available product to be used in our clinical trials, at acceptable prices, or at all;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- unanticipated serious safety concerns related to the use of our product candidates or any other product candidate;
- our cash position, and any changes in financial estimates by us or by any equity research analysts who might cover our stock;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt;
- conditions or trends in our industry;
- investors' general perception of our company and our business;
- our ability to effectively manage our growth;
- overall performance of the equity markets;
- changes in the market valuations and stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, capital commitments or divestitures;
- third-party publications and discussions about our business on social media, forums and other websites;
- recruitment or departure of key personnel;
- trading volume of our common stock;
- sales of common stock by us or our stockholders in the future;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- regulatory or legal developments in the U.S. and foreign countries;
- general political and economic conditions; and

- other events or factors, many of which are beyond our control.

The stock market in general, and the market for 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 common stock, regardless of our actual operating performance. The realization of any of the risks described in this section, or any of a broad range of other risks, could have a material adverse impact on the market price of our common stock. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted, could result in substantial costs and divert management's attention and resources.

We may not be able to maintain a listing of our common stock on Nasdaq.

Because our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may significantly reduce the value of our shares to a potential acquirer or make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a two-thirds (2/3) vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders' best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation of our common stock, if any, will be our stockholders' sole source of gains and they may never receive a return on their investment.

Our stockholders should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, the Exchange Act, the respective rules and regulations promulgated thereunder or the Federal Forum Provision. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

The structure of our common stock may limit our stockholders' ability to influence corporate matters and may limit their visibility with respect to certain transactions.

The structure of our common stock, which includes a series of non-voting common stock, may also limit our stockholders' ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. We do not currently have any shares of non-voting common stock outstanding. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation.

General Risk Factors

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, or fail, we could experience adverse consequences resulting from such compromise, or failure, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process, collect, receive, store, use, transfer, protect, secure, dispose of, transmit, and share collectively referred to as processing, data and information, including proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property and trade secrets, collectively referred to as sensitive information. The secure processing, maintenance and transmission of sensitive information is critical to our operations. Despite our security measures, our information technology and infrastructure, and that of the third parties upon which we rely, may be vulnerable to attacks by hackers or other third parties or breaches due to employee error, malfeasance or other disruptions.

Cyber-attacks, malicious internet-based activity, online and offline fraud, security breaches and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities.

These risks, as well as the number and frequency of cybersecurity events globally, may also be heightened during times of war or other major conflicts. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing attacks), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software, or hardware failures, loss of data or other information technology assets, adware, electrical and telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm and diversion of funds.

We have a hybrid in-office/remote work environment, which, like other companies that have incorporated remote working, has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

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

We currently rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, employee email, and other functions. We also currently rely on commercially available tools from third-party service providers to process and safeguard our sensitive information and business data. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Although, to our knowledge, we have not experienced any material security breach to date, we have experienced and may continue to experience threats or system failures which could cause a security incident or other interruption that could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. We have not yet conducted any internal audits or penetration tests on our information technology systems, however, we have enlisted a third-party to conduct security audits or penetration tests on our behalf, and we intend to undertake such testing. Such assessments, when conducted, could indicate vulnerabilities in our information technology systems which we may not be able to effectively remediate. If a security incident were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approvals efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption, security breach, or other incident results in a loss of or damage to our data or applications, other data or applications relating to our technology, or our current or future product candidates, we could incur liabilities and the further development of our current or future product candidates could be compromised or delayed. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents.

Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures have been or will be effective. Additionally, certain federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from breaches experienced by us or the third parties upon whom we rely. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We may not be able to detect and remediate vulnerabilities in our information technology systems because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. It is not possible to prevent all threats to our information technology systems and those of our third-party service providers, over which we exert less control, and any controls we implement to do so may prove to be ineffective.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays or disruptions in our clinical trials and development of product candidates, deter customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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

In the ordinary course of business, we and the third parties on which we rely process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about clinical trial participants and sensitive third-party data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. In the U.S., there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, transfer, security and processing of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to HIPAA, which imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Depending on the facts and circumstances, we could be subject to criminal penalties under certain privacy laws, including under HIPAA, for example, if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Furthermore, other states have proposed or enacted legislation that is focused on more narrow aspects of privacy. For example, a number of states have passed laws that protect biometric information and a smaller number of states have passed or are considering laws that are specifically focused upon health privacy, such as Washington's My Health My Data Act. The My Health My Data Act imposes new state restrictions and requirements on the processing and sale of consumer health data and creates a private right of action. In addition, all 50 U.S. states and the District of Columbia have enacted breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential information experienced by us or our collaborators or third-party service providers. The effects of state and federal privacy laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, in our clinical trials in Europe and/or the UK, our processing of personal data is subject to the European Union's General Data Protection Regulation, EU GDPR, and/or the United Kingdom's so-called "UK GDPR," together, the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that are subject to it, including relating to having a legal basis for processing personal data, relating to the processing of sensitive data (such as health data), obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, notification of data breaches, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union and the UK, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million) or 4% of annual global revenues, whichever is greater. 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.

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

Through executive and legislative action, the U.S. federal government has also taken steps to restrict data transactions involving persons affiliated with countries of concern such as China and Russia. For example, Executive Order 14117 on "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern" as implemented by Department of Justice regulations (issued in December 2024, with the final rule effective April 2025) prohibits data brokerage transactions involving certain sensitive personal data categories to countries of concern. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions. The evolving complexity of privacy and data security legislation in the U.S. may complicate our compliance efforts and further increase our risk of regulatory enforcement, penalties and litigation.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. If any privacy policies, marketing materials and other statements regarding data privacy and security that we publish are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, including the Federal Trade Commission, or other adverse consequences.

Laws and regulations related to privacy, data protection and security are continuing to evolve and are becoming increasingly stringent. Additionally, these laws may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions, creating uncertainty. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to the ways in which we collect and process data, our information technologies, systems and to exercise greater oversight and control over third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties we rely on fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we may face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials and development of product candidates); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our use of new and evolving technologies, such as AI, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability

The use of artificial intelligence in our operations and products may introduce new cybersecurity and data privacy risks, including vulnerabilities in artificial intelligence algorithms, unauthorized data access, unintended bias in automated decision-making, potential for artificial intelligence systems to process or generate personal data in ways that violate data privacy regulations, inadvertent exposure of confidential business information or trade secrets, and potential liability for discriminatory outcomes from artificial intelligence systems. In addition, if we enable or use solutions that draw controversy due to perceived or actual negative societal impact or otherwise cause harm, we may experience brand or reputational harm, competitive harm, legal liability, and defensive costs and expenses. These artificial intelligence-related risks may be difficult to detect, prevent, or remediate, and could result in regulatory investigations, fines, litigation, reputational damage, and increased compliance costs as well as impact our financial condition and results of operations.

A growing number of lawmakers are adopting laws and regulations addressing, and have focused enforcement efforts on, the development and adoption of AI technologies and use of such technologies in compliance with ethical standards and societal expectations. In the U.S., several states have passed laws to regulate various uses of AI, including to make consequential decisions, among other requirements, that were set to take effect in 2026. In addition, it is possible that U.S. states and the federal government will adopt new laws and regulations in the near future, and that existing laws and regulations may be interpreted in ways that would affect our business and the ways in which we and our customers use our AI technologies. The Executive Order on Ensuring a National Policy Framework for Artificial Intelligence, which was signed on December 11, 2025, raises significant questions regarding the future of these state laws and it is likely that companies making use of AI technologies will face a uncertain legal framework for the near future,

Outside the U.S., lawmaking and regulation relating to AI is proceeding at a similar pace. In Europe, for example, the EU's Artificial Intelligence Act, or AI Act, entered into force on August 1, 2024 and, with some exceptions, will begin to apply as of August 2, 2026. This legislation imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. As we continue to develop and use AI systems that are governed by the AI Act or other emerging regulations, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific ethical, accountability, and administrative requirements, some of which may increase our costs and compliance obligations. Further, potential government regulation related to AI use and ethics may also increase the cost of research and development in this area, and failure to properly remediate AI usage or ethics issues may cause public confidence in AI to be undermined, which could slow adoption of AI in our products and services.

The rapid evolution of AI technologies and the applicable regulatory frameworks governing AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in a legally compliant and socially responsible manner and to minimize any real or perceived unintended harmful impacts of the use of such technologies. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools. Our vendors may also incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including through the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We are subject to governmental export and import controls, economic sanctions, anti-corruption laws and regulations of the U.S. and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which could harm our business.

We are subject to and required to comply with various export control, import and trade and economic sanctions laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. These laws may prohibit or restrict our ability to transfer, sell or supply, our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo.

We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws, including the FCPA, generally prohibit companies and their employees, agents, CROs, contractors and other partners from offering, promising, giving, soliciting or authorizing others to give or receive anything of value, either directly or indirectly, to or from a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we fail to maintain an effective system of internal controls over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our second annual report on Form 10-K for the fiscal year ending December 31, 2027, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. In addition, when we lose our status as an "emerging growth company" and if we do not otherwise qualify as a "non-accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting, which will require additional expense, resources and management commitment.

We may identify material weaknesses in our system of internal controls over financial reporting that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We might not be able to utilize a significant portion of our net operating loss carryforwards, which could harm our profitability.

We have generated, and expect to continue to generate, significant federal and state net operating loss carryforwards, or NOLs. As of December 31, 2025, we had federal and state NOLs of $190.3 million and $13.4 million, respectively. Under current tax laws and regulations, these NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in taxable years beginning after December 31, 2017 generally may be carried forward indefinitely, but the deductibility of such federal NOLs is limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by one or more "5 percent shareholders" over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes as a result of our IPO and/or subsequent shifts in our stock ownership (some of which are outside our control). There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, portions of our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, or taxes could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

U.S. federal, state, local, and foreign tax laws, regulations and administrative guidance are subject to change as a result of the legislative process and review and interpretation by the U.S. Internal Revenue Service, or IRS, the U.S. Treasury Department and other taxing authorities. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. For example, on July 4, 2025, President Donald Trump signed the One Big Beautiful Bill Act into law. Key tax provisions included the restoration of 100% bonus depreciation for certain qualified property, immediate expensing for domestic research and experimental expenditures and the ability to make elective adjustments for prior years, changes to the Section 163(j) interest limitations and updates to net CFC tested income (formerly GILTI) and FDII rules. In recent years, many other similar changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, financial condition, results of operations, or cash flow. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

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

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure in this Quarterly Report;
- 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 the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means, among other conditions, that the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies, and we expect to rely on this exemption. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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

As a public company, we incur significant additional legal, accounting and other costs that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will increase our net loss, and may require us to reduce costs in other areas of our business.

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

Our operations could be adversely affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, inflation, declines in economic growth, global supply chain disruptions, and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, including the ongoing war in Ukraine and the ongoing hostilities in the Middle East as well as the increasingly strained relationship between the U.S. and China. Sanctions or tariffs imposed by the U.S. and other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We may become involved in litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

We have in the past and may in the future be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. For example, on June 1, 2017, Genoa, a QoL Healthcare Company, LLC filed a lawsuit against us for trademark infringement which resulted in our company changing its name to the current name. Additionally, from November 2020 through July 2024, Avalyn was involved in a dispute on matters related to a Stock Purchase Agreement that concluded in a confidential settlement agreement. We may be exposed to similar litigation even if no wrongdoing on our part has occurred. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows, and we may not have insurance coverage for such claims or our insurance coverage may not adequately cover all costs and damages related to such claims. Moreover, adverse publicity about legal action against us could damage our reputation and brand image, even if the legal action is unfounded or not material to our operations.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from our Initial Public Offering

On April 29, 2026, the SEC declared effective our registration statement on Form S-1 (File No. 333-294932), as amended, or the Registration Statement, filed in connection with our IPO. Pursuant to the Registration Statement, we registered the offer and sale of 16,666,667 shares of our common stock with a maximum aggregate offering price of approximately $300.0 million. Morgan Stanley, Jefferies, Evercore ISI, and Guggenheim Securities acted as representatives of the underwriters for the IPO.

We received net proceeds of approximately $316.6 million from the sale of 19,166,667 shares of common stock at a price of $18.00 per share, which included 2,500,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our IPO Prospectus.

(c) Issuer Repurchases of Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c) During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K, except as set forth below:

Name and Position	Action Taken	Nature of Trading Arrangement	Plan Start Date	Plan End Date	Aggregate Number of Securities
Lyn Baranowski (Chief Executive Officer and Director)	Adoption (July 30, 2026)	Trading plan intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c)	November 17, 2026	July 15, 2027	Up to 300,000 shares
Douglas Carlson (Chief Financial Officer)	Adoption (July 30, 2026)	Trading plan intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c)	November 17, 2026	July 15, 2027	Up to 85,000 shares
Howard Lazarus (Chief Medical Officer)	Adoption (July 30, 2026)	Trading plan intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c)	November 17, 2026	February 15, 2027	Up to 76,000 shares
Melissa Rhodes (Chief Operating Officer)	Adoption (July 30, 2026)	Trading plan intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c)	November 17, 2026	July 15, 2027	Up to 76,000 shares

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Avalyn Pharma Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 1, 2026 (File No. 001-43251)).
3.2	Amended and Restated Bylaws of Avalyn Pharma Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on May 1, 2026 (File No. 001-43251)).
4.1†+	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated as of April 25, 2025 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-294932)).
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-294932)).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

† Certain portions of this document that constitute confidential information have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

\+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

SIGNATURES

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

Avalyn Pharma Inc.

Date: November 12, 2026

By: /s/ Lyn Baranowski
Lyn Baranowski
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 12, 2026

By: /s/ Douglas Carlson
Douglas Carlson
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Lyn Baranowski, certify that:

1. I have reviewed this Form 10-Q for the quarterly period ended September 30, 2026 of Avalyn Pharma Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   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;

   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: November 12, 2026

By: /s/ Lyn Baranowski
Lyn Baranowski
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Douglas Carlson, certify that:

1. I have reviewed this Form 10-Q for the quarterly period ended September 30, 2026 of Avalyn Pharma Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    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;

    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: November 12, 2026

By: /s/ Douglas Carlson
Douglas Carlson
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

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

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

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

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

Date: November 12, 2026

By: /s/ Lyn Baranowski
Lyn Baranowski
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 Avalyn Pharma Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 12, 2026

By: /s/ Douglas Carlson
Douglas Carlson
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)