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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

or

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

For the transition period from _____ to_____

Commission File Number: 001-42143

Alumis Inc.

(Exact name of registrant as specified in its charter)

Delaware	**86-1771129**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

280 East Grand Avenue
South San Francisco, CA 94080
(Address of Principal Executive Offices)

(650) 231-6625
(Registrant's telephone number)

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 ☒

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Stock, par value $0.0001 per share	ALMS	**The Nasdaq Global Select Market**

As of November 5, 2026, the registrant had 129,820,970 shares of voting common stock, $0.0001 par value per share, and zero shares of non-voting common stock, $0.0001 par value per share, outstanding.

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In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Alumis," "the Company," "we," "us," "our" and similar references refer to Alumis Inc.

This Quarterly Report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates, and continue as a going concern;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including our plans to submit a New Drug Application ("NDA") for envudeucitinib ("envu"), formerly known as ESK-001, in moderate-to-severe plaque psoriasis ("PsO") by the end of 2026;
- the potential for envu to meaningfully elevate care for and effectively reduce the full burden of disease for patients with PsO;
- our plans relating to the research and development of our product candidates, including the timing of clinical trial initiation and related preparatory work, clinical trial progress and results, as well as clinical trial completion;
- developments related to our competitors and our industry, including the success of competing product candidates and therapies that are, or may become, available;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our expectations regarding the potential benefits from our existing or any future license or collaboration agreements, including the receipt of potential co-development, milestone and royalty payments;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our beliefs regarding the potential of our product candidates to demonstrate differentiation from other approved therapies or product candidates in development;

- the ability to obtain and, if approved, maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates and technology and not infringe, misappropriate or otherwise violate the intellectual property of others;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), and a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

You should refer to the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate.

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 on Form 10-Q, and although 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 a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

ALUMIS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share and per share amounts)	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 57,691	$ 89,670
Restricted cash	—	82
Marketable securities, current	373,647	218,831
Research and development prepaid expenses	3,437	2,909
Other prepaid expenses and current assets	7,815	6,740
Total current assets	442,590	318,232
Restricted cash, non-current	1,388	1,301
Property and equipment, net	16,427	18,190
Intangible assets	9,135	50,959
Operating lease right-of-use assets, net	16,744	16,971
Other assets, non-current	2,427	6,287
Total assets	$ 488,711	$ 411,940
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,926	$ 10,106
Research and development accrued expenses	40,243	34,781
Other accrued expenses and current liabilities	18,331	22,303
Deferred revenue, current	6,876	1,458
Operating lease liabilities, current	5,029	4,670
Total current liabilities	79,405	73,318
Operating lease liabilities, non-current	30,277	32,244
Deferred tax liability	384	2,140
Deferred revenue, non-current	—	2,611
Other liabilities, non-current	220	330
Total liabilities	110,286	110,643
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 50,000,000 shares authorized, zero shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, voting, $0.0001 par value; 492,815,092 voting shares authorized as of September 30, 2026 and December 31, 2025; 129,680,481 and 99,084,365 voting shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	13	9
Common stock, non-voting, $0.0001 par value; 7,184,908 non-voting shares authorized as of September 30, 2026 and December 31, 2025; zero and 5,622,408 non-voting shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	1
Additional paid-in capital	1,611,173	1,202,975
Accumulated other comprehensive income (loss)	(730)	188
Accumulated deficit	(1,232,031)	(901,876)
Total stockholders' equity	378,425	301,297
Total liabilities and stockholders' equity	$ 488,711	$ 411,940

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

ALUMIS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(in thousands, except share and per share amounts)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Revenue:				
License revenue	$ —	$ —	$ —	$ 17,389
Collaboration revenue	1,907	2,066	5,310	4,732
Total revenue	1,907	2,066	5,310	22,121
Operating expenses:				
Research and development expenses, including related party expenses of $80, $287, $545 and $808 for the three and nine months ended September 30, 2026 and 2025, respectively	80,792	97,836	247,669	303,213
General and administrative expenses	20,191	19,522	62,157	76,267
Intangible assets impairment loss	—	—	41,824	—
Total operating expenses	100,983	117,358	351,650	379,480
Loss from operations	(99,076)	(115,292)	(346,340)	(357,359)
Other income (expense):				
Gain on bargain purchase	—	—	—	187,907
Interest income	4,304	4,594	14,601	10,633
Other income (expenses), net	(109)	(54)	(173)	(136)
Total other income (expense), net	4,195	4,540	14,428	198,404
Net loss before income taxes	(94,881)	(110,752)	(331,912)	(158,955)
Income tax benefit	—	—	1,757	8,561
Net loss	$ (94,881)	$ (110,752)	$ (330,155)	$ (150,394)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net	(47)	212	(918)	194
Total comprehensive loss	$ (94,928)	$ (110,540)	$ (331,073)	$ (150,200)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.73)	$ (1.06)	$ (2.59)	$ (1.92)
Weighted-average shares of common stock outstanding, basic and diluted	129,293,849	104,109,243	127,360,394	78,471,407

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

ALUMIS INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2025	**104,706,773**	**$ 10**	**$ 1,202,975**	**$ 188**	**$ (901,876)**	**$ 301,297**
Issuance of common stock in public offering, net of underwriting discounts, commissions and offering costs of $21,260	20,297,500	2	323,797	—	—	323,799
Issuance of common stock upon exercise of stock options	2,177,964	—	23,265	—	—	23,265
Issuance of common stock upon vesting of restricted stock units	47,509	—	—	—	—	—
Vesting of early exercised stock options	—	—	29	—	—	29
Stock-based compensation expense	—	—	12,339	—	—	12,339
Other comprehensive income (loss), net	—	—	—	(655)	—	(655)
Net income (loss)	—	—	—	—	(93,053)	(93,053)
Balance at March 31, 2026	**127,229,746**	**$ 12**	**$ 1,562,405**	**$ (467)**	**$ (994,929)**	**$ 567,021**
Issuance of common stock upon exercise of stock options	1,001,393	—	11,708	—	—	11,708
Issuance of common stock upon vesting of restricted stock units	21,156	—	—	—	—	—
Issuance of common stock under the 2024 Employee Stock Purchase Plan	253,150	—	1,570	—	—	1,570
Vesting of early exercised stock options	—	—	23	—	—	23
Stock-based compensation expense	—	—	14,273	—	—	14,273
Other comprehensive income (loss), net	—	—	—	(216)	—	(216)
Net income (loss)	—	—	—	—	(142,221)	(142,221)
Balance at June 30, 2026	**128,505,445**	**$ 12**	**$ 1,589,979**	**$ (683)**	**$ (1,137,150)**	**$ 452,158**
Issuance of common stock upon exercise of stock options	570,468	1	6,889	—	—	6,890
Issuance of common stock upon vesting of restricted stock units	604,568	—	—	—	—	—
Vesting of early exercised stock options	—	—	19	—	—	19
Stock-based compensation expense	—	—	14,286	—	—	14,286
Other comprehensive income (loss), net	—	—	—	(47)	—	(47)
Net income (loss)	—	—	—	—	(94,881)	(94,881)
Balance at September 30, 2026	**129,680,481**	**$ 13**	**$ 1,611,173**	**$ (730)**	**$ (1,232,031)**	**$ 378,425**

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

ALUMIS INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2024	**54,407,327**	**$ 5**	**$ 918,610**	**$ 40**	**$ (658,551)**	**$ 260,104**
Vesting of early exercised stock options	—	—	224	—	—	224
Vesting of restricted shares of common stock	—	—	2	—	—	2
Stock-based compensation expense	—	—	6,995	—	—	6,995
Other comprehensive income (loss), net	—	—	—	(48)	—	(48)
Net income (loss)	—	—	—	—	(98,963)	(98,963)
Balance at March 31, 2025	**54,407,327**	**$ 5**	**$ 925,831**	**$ (8)**	**$ (757,514)**	**$ 168,314**
Issuance of common stock and equity awards in connection with the ACELYRIN Merger	48,653,549	5	238,072	—	—	238,077
Issuance of common stock upon vesting of restricted stock units	798,751	—	—	—	—	—
Issuance of common stock under the 2024 Employee Stock Purchase Plan	184,633	—	766	—	—	766
Vesting of early exercised stock options	—	—	184	—	—	184
Repurchase of common stock issued upon early exercise of stock options	(1,783)	—	—	—	—	—
Stock-based compensation expense	—	—	18,635	—	—	18,635
Other comprehensive income (loss), net	—	—	—	30	—	30
Net income (loss)	—	—	—	—	59,321	59,321
Balance at June 30, 2025	**104,042,477**	**$ 10**	**$ 1,183,488**	**$ 22**	**$ (698,193)**	**$ 485,327**
Issuance of common stock upon vesting of restricted stock units	316,662	—	—	—	—	—
Vesting of early exercised stock options	—	—	199	—	—	199
Stock-based compensation expense	—	—	9,787	—	—	9,787
Other comprehensive income (loss), net	—	—	—	212	—	212
Net income (loss)	—	—	—	—	(110,752)	(110,752)
Balance at September 30, 2025	**104,359,139**	**$ 10**	**$ 1,193,474**	**$ 234**	**$ (808,945)**	**$ 384,773**

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

ALUMIS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)	Nine Months Ended September 30, 2026	2025
Cash flows from operating activities		
Net loss	$ (330,155)	$ (150,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Intangible assets impairment loss	41,824	—
Stock-based compensation	40,898	35,417
Net accretion of discounts on marketable securities	(5,548)	(3,876)
Depreciation and amortization	2,628	2,629
Non-cash lease expense	1,617	1,161
Impairment of long-lived assets	444	529
Gain on bargain purchase in connection with the ACELYRIN Merger	—	(187,907)
Changes in operating assets and liabilities:		
Research and development prepaid expenses	(528)	9,426
Other prepaid expenses and other assets	(1,075)	13,346
Other assets, non-current	3,860	(5,073)
Accounts payable	(1,180)	(11,586)
Research and development accrued expenses	5,462	4,935
Other accrued expenses and current liabilities	(3,972)	2,554
Deferred revenue	2,808	1,944
Operating lease liabilities	(3,442)	(2,328)
Other liabilities, non-current	(37)	168
Deferred tax liability	(1,757)	(8,561)
Net cash used in operating activities	(248,153)	(297,616)
Cash flows from investing activities		
Maturities of marketable securities	353,684	305,423
Purchases of marketable securities	(503,869)	(161,648)
Purchases of property and equipment	(865)	(653)
Cash, cash equivalents and restricted cash acquired in connection with the ACELYRIN Merger	—	49,742
Net cash (used in) provided by investing activities	(151,050)	192,864
Cash flows from financing activities		
Proceeds from public offering of common stock, net of underwriter discounts, commissions and offering costs	323,797	—
Proceeds from issuance of common stock upon exercise of stock options	41,862	—
Proceeds from issuance of common stock under the 2024 Employee Stock Purchase Plan	1,570	766
Repurchase of common stock issued upon early exercise of stock options	—	(17)
Net cash provided by financing activities	367,229	749
Net decrease in cash, cash equivalents and restricted cash	(31,974)	(104,003)
Cash, cash equivalents and restricted cash at beginning of period	91,053	170,632
Cash, cash equivalents and restricted cash at end of period	$ 59,079	$ 66,629
Supplemental disclosures:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,835	$ 1,776
Vesting of early exercised stock options and unvested restricted shares of common stock	$ 71	$ 609
Equity consideration transferred in connection with the ACELYRIN Merger	$ —	$ 238,077
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 57,691	$ 65,257
Restricted cash, non-current	1,388	1,372
Total cash, cash equivalents and restricted cash	$ 59,079	$ 66,629

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

ALUMIS INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Nature of the Business

Organization and Business

Alumis Inc. (the "Company") is a clinical stage biopharmaceutical company focused on identifying, acquiring and accelerating the development and commercialization of transformative medicines for autoimmune disorders. The Company leverages its proprietary precision data analytics platform, biological insights, and a team of experts with deep experience in precision medicine drug discovery, development, and immunology, in its mission to create medicines that significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies.

The Company was founded on January 29, 2021, as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.'s name was changed to Esker Therapeutics, Inc. on March 8, 2021, and to Alumis Inc. on January 6, 2022. The Company is headquartered in South San Francisco, California.

As of September 30, 2026, the Company had one wholly owned subsidiary, ACELYRIN, Inc. ("ACELYRIN"), a Delaware corporation incorporated on July 27, 2020. Arrow Merger Sub, Inc. ("Merger Sub"), the Company's wholly owned subsidiary incorporated in January 2025, was merged with and into ACELYRIN in May 2025. ACELYRIN's wholly owned subsidiary, WH2, LLC, was dissolved in September 2026.

ACELYRIN Merger

On February 6, 2025, the Company entered into an Agreement and Plan of Merger, and, on April 20, 2025, the Company entered into an Amendment to Agreement and Plan of Merger (collectively the "Merger Agreement") with ACELYRIN and Merger Sub, a Delaware corporation and a direct wholly owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into ACELYRIN, with ACELYRIN continuing as a direct wholly owned subsidiary of the Company (the "ACELYRIN Merger"). The Merger Agreement was approved by the disinterested directors on the Company's board of directors and the board of directors of ACELYRIN and was approved by the stockholders of each company on May 13, 2025. On May 21, 2025, the Company completed the ACELYRIN Merger with ACELYRIN for a purchase consideration of $238.1 million that included the issuance of 48,653,549 shares of the Company's common stock and the fair value of replacement awards attributable to pre-combination services, to acquire net assets with a fair value of $426.0 million. See Note 3 for additional information.

Public Offering of Common Stock

On January 7, 2026, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Morgan Stanley & Co. LLC, Leerink Partners LLC and Cantor Fitzgerald & Co. ("Cantor") (collectively the "Underwriters"), relating to the issuance and sale in a public offering of 17,650,000 shares of the Company's common stock at a price of $17.00 per share. In addition, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to 2,647,500 additional shares of common stock at the public offering price, less the underwriting discounts and commissions, which was exercised in full on January 8, 2026. On January 9, 2026, the offering closed and the Company received net proceeds of $324.4 million, after deducting underwriting discounts and commissions.

The offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-288510) that was filed with the U.S. Securities and Exchange Commission ("SEC") on July 3, 2025 and declared effective by the SEC on August 19, 2025, and related prospectus and prospectus supplement thereunder.

Controlled Equity Offering℠

On March 18, 2026, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor as sales agent, pursuant to which the Company may offer and sell, from time to time through Cantor, at its option, shares of its common stock having an aggregate offering price of up to $300.0 million (the "ATM Shares"). The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through the Nasdaq Global Select Market. The Company agreed to pay Cantor a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by Cantor. As of the date of issuance of these financial statements, no ATM Shares have been sold under the Sales Agreement.

Liquidity

The Company has incurred negative operating cash flows and significant losses from operations since its inception. Net loss was $94.9 million and $110.8 million for the three months ended September 30, 2026 and 2025, respectively, and $330.2 million and $150.4 million for the nine months ended September 30, 2026 and 2025, respectively. Cash used in operating activities was $248.2 million and $297.6 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, the Company had an accumulated deficit of $1,232.0 million.

The Company has historically funded its operations primarily through the issuance of common stock, including in connection with the ACELYRIN Merger and the Company's initial public offering ("IPO") and a concurrent private placement transaction, the issuance of redeemable convertible preferred stock and convertible promissory notes in private placements, and, most recently, the public offering of common stock which closed on January 9, 2026, as well as cash payments received under the collaboration and license agreement (the "Kaken Collaboration Agreement") with Kaken Pharmaceutical Co., Ltd. ("Kaken").

The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company does not expect to generate any revenue from commercial product sales unless and until it successfully completes development and obtains regulatory approval for one or more of its product candidates. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital.

The Company believes that, based on its current operating plan, its existing cash, cash equivalents and marketable securities of $431.3 million as of September 30, 2026, will not be sufficient to meet its operating and capital requirements for at least 12 months from the date of issuance of these unaudited condensed consolidated financial statements and there is substantial doubt about the Company's ability to continue as a going concern.

The Company will need to raise significant additional capital to fund ongoing research and development activities, support potential commercialization including market and launch preparation activities and maintain future operations. The Company's management plans to monitor operating expenses and may reduce its operating expenses and may raise additional capital through a combination of public and private equity, debt financings, strategic alliances and licensing arrangements. For example, the Company may scale back or discontinue clinical development activities and reallocate its working capital to extend its ability to meet its operating and capital requirements. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, on terms that are favorable, the Company could be required to delay, scale back, or abandon some or all of its planned development programs and other operations, which could materially harm the Company's business, financial condition and results of operations.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal

course of business. The accompanying unaudited condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies and Basis of Presentation

The significant accounting policies and estimates used in the preparation of the accompanying unaudited condensed consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2025 included in the Company's Annual Report on Form 10-K filed with the SEC on March 19, 2026. There have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2026.

Basis of Presentation

The condensed consolidated financial statements and accompanying notes are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting and do not contain all information that is included in the annual financial statements and notes thereto of the Company.

The Company's unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, and all intercompany balances and transactions have been eliminated in consolidation. The results of ACELYRIN and its wholly owned subsidiary, WH2, LLC, have been included in the condensed consolidated financial statements from the closing of the ACELYRIN Merger. WH2, LLC had no operations or balances from the closing of the ACELYRIN Merger through its dissolution in September 2026. The accounts of Merger Sub were included in the condensed consolidated financial statements from its incorporation in January 2025 until the closing of the ACELYRIN Merger, when Merger Sub merged with and into ACELYRIN.

The unaudited 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 statement of the Company's financial position as of September 30, 2026 and its results of 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 condensed balance sheet as of December 31, 2025, included in this filing, was derived from audited annual consolidated financial statements but does not include all disclosures required by U.S. GAAP. The results of operations for the three and nine months ended September 30, 2026 and 2025 are not necessarily indicative of the results of operations to be expected for the full year or for any other subsequent interim period.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to accrued research and development expenses, valuation of acquired in-process research and development ("IPR&D") intangible assets, revenue recognition, and stock-based compensation expense. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the

results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment, which is the business of researching and developing medicines for autoimmune disorders. The chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. See Note 15 for additional information. All of the Company's long-lived assets are located in the United States.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents, investments in marketable securities, accounts receivable and restricted cash. The Company maintains bank deposits in federally insured financial institutions and certain of these deposits exceed federally insured limits. To date, the Company has not experienced any losses on its deposits of cash and periodically evaluates the creditworthiness of the financial institutions at which its bank deposits are maintained.

The Company also invests in money market funds, U.S. Treasury obligations, commercial paper, corporate debt obligations, supranational debt obligations, and government development bank obligations, which can be subject to certain credit risks. The Company mitigates credit risk by limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions at which investments are maintained and of the issuers of the marketable securities. To date, the Company has not experienced any loss of principal on its financial instruments.

The Company considers a customer to be significant when revenues from that customer represent 10% or more of total revenues. All of the Company's revenue recognized in its condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, was earned under its license and collaboration agreement with Kaken. As a result, the Company is subject to customer concentration risk. To date, the Company has not incurred any credit losses in connection with the Kaken Collaboration Agreement.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the Company's ability to advance the development of its proprietary precision data analytics platform, timing and ability to advance its product candidates through preclinical and clinical development; costs and timelines associated with the manufacturing of clinical supplies; regulatory approval, market acceptance of, and reimbursement for, any product candidates the Company may develop; performance of third-party vendors; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; protection of intellectual property; litigation or claims against the Company based on intellectual property or other factors; and its ability to attract and retain employees necessary to support its growth.

Further, the Company's business and results of operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges and uncertainty in the markets, including international trade policies and tariffs, severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability. The United States and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, including tariffs targeting pharmaceutical products and related inputs, and could continue to significantly increase tariffs on a broad array of goods. Similarly, the Company's financial condition and results of operations may continue to

be affected by global economic uncertainty, general market volatility and geopolitical tensions, including the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the United States, Israel and Iran. Escalation or expansion of these conflicts, as well as related sanctions, export controls, trade restrictions and the disruption of global energy markets, fuel prices, transportation networks, and supply chains, may disrupt or otherwise negatively impact the Company's supply chain and increase its costs. These geopolitical developments, together with evolving global economic conditions, trade policies and broader macroeconomic conditions may negatively impact the Company's business, financial position and results of operations.

Intangible Assets

Intangible assets related to acquired IPR&D are considered to be indefinite-lived until abandonment or completion of the associated research and development efforts, which generally occurs when regulatory approval is obtained. Indefinite-lived intangible assets are not amortized and, instead, are tested for impairment annually in the fourth quarter, or more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired as required by ASC 350 *Intangibles - Goodwill and Other* ("ASC 350"). Such events and circumstances may include significant changes in the Company's business climate, economic and industry trends, legal or regulatory factors, clinical trial results, significant competition or changes in development strategy.

The Company may first perform a qualitative assessment to determine whether it is necessary to perform a quantitative impairment test. Alternatively, the Company may elect to proceed directly to a quantitative impairment test. The quantitative impairment test compares the fair value of the indefinite-lived intangible asset with its carrying amount. If the carrying amount exceeds fair value, an impairment loss is recognized for the excess and the carrying amount of the asset is reduced accordingly. After an impairment loss is recognized, the adjusted carrying amount of the intangible asset becomes its new accounting basis.

In determining the initial fair value of an intangible asset, or when quantitative analysis is required to determine any impairment, the Company usually uses an income approach that discounts expected future cash flows to present value using a discount rate that is based on the estimated weighted-average cost of capital for comparable companies and represents the rate that market participants would use to value the intangible asset. These cash flow models require the use of Level 3 fair value measurements and inputs, including estimated revenues, costs and probabilities of achieving technical and regulatory milestones, among other factors. In June 2026, the Company recognized an impairment loss related to its acquired IPR&D intangible asset. See Note 6 for additional information.

Intangible assets with finite useful lives, which include completed IPR&D projects, are amortized over their estimated useful lives, primarily on a straight-line basis, and are also periodically reviewed for changes in facts or circumstances that may result in an impairment or in a reduction to the estimated useful life of the asset.

Development costs incurred after an acquisition are expensed as they are incurred.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood of deferred tax assets being realized. It provides a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences

representing net future deductible amounts become deductible.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties incurred in relation to unrecognized tax benefits.

Income tax benefit was zero and $1.8 million for the three and nine months ended September 30, 2026, respectively, as compared to zero and $8.6 million for the three and nine months ended September 30, 2025, respectively. In June 2026, in connection with the impairment of the Company's intangible assets, the Company recognized a benefit from income taxes of $1.8 million, which was primarily related to the reduction of deferred tax liabilities, partially offset by an increase in valuation allowance resulting from the measurement of its acquired IPR&D intangible asset at fair value in connection with an impairment assessment. In the three months ended June 30, 2025, in connection with the ACELYRIN Merger, the Company recognized a benefit from income taxes of $8.6 million, which was primarily related to the realization of deferred tax assets and the release of the related valuation allowance.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the JOBS Act, and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

Recently Adopted Accounting Pronouncements

In July 2025, the FASB issued *ASU 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* ("ASU 2025-05") which provides a practical expedient and accounting policy election related to estimating expected credit losses for certain receivables and contract assets. The Company adopted ASU 2025-05 as of January 1, 2026. Adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recently Issued and Not Yet Adopted Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Topic 220)* ("ASU 2024-03"), requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. The amendments of ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The requirements of ASU 2024-03 may be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting ASU 2024-03 on its consolidated financial statements and disclosures.

3. Acquisition

ACELYRIN Merger

The Company completed its acquisition of ACELYRIN on May 21, 2025 (the "Closing Date") and accounted for the transaction as an acquisition under ASC Topic 805, *Business Combinations*. ACELYRIN was a late-stage biopharma company focused on identifying, acquiring and accelerating the development and commercialization of transformative medicines. ACELYRIN's portfolio consisted of lonigutamab, a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the potential treatment of Thyroid Eye Disease ("TED"). The ACELYRIN Merger strengthened the Company's balance sheet and its cash position and added the lonigutamab product candidate to the Company's development portfolio as of the Closing Date. The ACELYRIN Merger was accounted for as a business combination with the Company being treated as the accounting acquirer.

As of the Closing Date, the Company (i) issued 48,653,549 shares of its common stock in exchange for ACELYRIN's issued and outstanding common stock shares and paid cash for fractional shares, (ii) assumed ACELYRIN's stock options with an exercise price of $18.00 or less outstanding and unexercised immediately prior to the Closing Date, which were exercisable into 4,712,186 shares of the Company's common stock, (iii) assumed ACELYRIN's restricted stock units ("RSUs") outstanding and unvested immediately prior to the Closing Date, which were converted into 1,323,905 of the Company's RSUs, and (iv) assumed ACELYRIN's performance RSUs outstanding and unvested immediately prior to the Closing Date, which were converted into 146,963 of the Company's RSUs subject only to a service vesting condition.

Outstanding shares, stock options, RSUs and performance RSUs were exchanged at the exchange ratio of 0.4814 shares of the Company's common stock for each share of ACELYRIN's common stock (the "Exchange Ratio"). ACELYRIN's outstanding and unexercised stock options with exercise prices more than $18.00 were cancelled. Exercise prices for the assumed stock options were determined as the product of the original exercise prices multiplied by the reciprocal of the Exchange Ratio. Converted ACELYRIN stock options and RSUs continue to vest in accordance with their original terms. Assumed performance RSUs were deemed to have 100% satisfied their performance conditions and vest in two equal installments on May 15 of calendar years 2026 and 2027, subject to the holder of the converted performance RSUs remaining in service with the Company or any of its subsidiaries on such date.

The purchase price consideration consisted of the Company's shares of common stock issued as of the Closing Date and the additional stock-based compensation related to the fair value of replacement awards attributable to pre-combination services, and was calculated as follows (in thousands, except share and per share amounts):

Implied shares of common stock issued to holders of ACELYRIN common stock		48,653,549
Closing price per share of common stock as of Closing Date	$	4.78
Consideration transferred for share exchange	$	232,564
Fair value of replacement awards attributable to pre-combination services	$	5,513
Total purchase price consideration	$	238,077

The following table presents the final purchase price allocation of the fair value of the net assets acquired and liabilities assumed as of the Closing Date (in thousands):

Assets Acquired		
Cash and cash equivalents	$	49,155
Restricted cash		367
Marketable securities		333,436
Research and development prepaid expenses		958
Prepaid credit voucher for clinical manufacturing		11,376
Other prepaid expenses and current assets		8,081
Restricted cash, non-current		220
Property and equipment		420
Intangible assets		50,959
Operating lease right-of-use assets		4,349
Other assets, non-current		744
Total assets	**$**	**460,065**
Liabilities Assumed		
Accounts payable	$	(6,518)
Research and development accrued expenses		(3,546)
Other accrued expenses and current liabilities		(5,688)
Operating lease liabilities, current		(1,390)
Operating lease liabilities, non-current		(6,238)
Deferred tax liability		(10,701)
Total liabilities		**(34,081)**
Fair value of net assets	**$**	**425,984**
Purchase consideration		238,077
Gain on bargain purchase	**$**	**187,907**

Intangible assets consist of an acquired IPR&D intangible asset related to the lonigutamab product candidate that was in development as of the Closing Date. The acquired IPR&D intangible asset was initially recognized at a fair value of $51.0 million, determined using the multi-period excess earnings method, which reflected the present value of projected incremental after-tax cash flows attributable to the asset as of the Closing Date. The valuation utilized a discount rate of 24.0% representing management’s best estimate of a market participant's after-tax weighted-average cost of capital. Projected future cash flows were based on significant estimates, including estimated revenues, costs and probabilities of achieving technical and regulatory milestones, among other factors. See Note 6 for additional information.

The Company acquired a prepaid credit voucher for clinical manufacturing issued by one of ACELYRIN’s contract manufacturers that is applied toward payments of clinical product manufacturing invoices issued by the vendor. The balance of $11.4 million as of the Closing Date was not adjusted from its carrying amount as its fair value approximated its carrying value as of this date.

The Company acquired two operating leases and a sublease. See Note 10 for additional details. The Company estimated the fair value of lease liabilities as the present value of the remaining lease payments, as if the acquired leases were new leases of the acquirer as of the Closing Date. The Company measured the right-of-use asset at the same amount as the lease liability as adjusted to reflect favorable or unfavorable terms of the lease when compared with market terms. As ACELYRIN entered into a sublease in February 2025, these sublease terms were considered at market terms. As of the Closing Date, the fair value of operating lease liabilities, current, increased by $0.2 million and the fair value of operating lease liabilities, non-current, increased by $0.5 million.

Because the fair value of the identifiable assets acquired and liabilities assumed exceeded the fair value of the purchase consideration transferred, the Company recorded a gain on bargain purchase of $187.9 million as of the Closing Date. Consequently, the Company reassessed the recognition and measurement of identifiable assets acquired and liabilities assumed in accordance with ASC 805-30-25-4 and concluded that all acquired assets and assumed liabilities were recognized and that the valuation procedures and resulting measures were appropriate. Gain on bargain purchase was primarily related to the market value of ACELYRIN's common stock trading below the carrying value of net assets and the Exchange Ratio being fixed at the time the Merger Agreement was signed and not adjusted for subsequent changes in the market price of the Company's common stock. Gain on bargain purchase was recognized as other income in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2025. The Company recognized a deferred tax liability of $10.7 million related to the acquired IPR&D intangible asset as of the Closing Date.

The Company had additional severance-related obligations under the Merger Agreement that were separate from the assets and liabilities acquired in the Merger. In accordance with the ACELYRIN severance plan, ACELYRIN employees who were terminated without cause within 12 months of the Closing Date were entitled to severance benefits, including cash severance, accelerated vesting of outstanding equity awards and an extension of the post-termination exercise period of outstanding stock options of generally up to 12 months.

The Company estimated total cash severance obligation, including related payroll taxes, of $11.9 million. The severance obligation was recognized over the remaining requisite service periods of the affected employees and was substantially paid by December 31, 2025. The Company recognized $1.9 million as general and administrative expenses and $2.4 million as research and development expenses related to severance expenses for the three months ended September 30, 2025. The Company recognized $7.1 million as general and administrative expenses and $6.1 million as research and development expenses related to severance expenses for the nine months ended September 30, 2025. No severance expense was recognized for the three and nine months ended September 30, 2026.

The Company estimated stock-based compensation expense of $13.1 million related to the accelerated vesting of equity awards and the post-termination exercise period extensions granted to affected employees, which was fully recognized during the year ended December 31, 2025. The Company recognized stock-based compensation expense of $2.1 million related to these arrangements for the three months ended September 30, 2025, consisting of $1.0 million in general and administrative expenses and $1.1 million in research and development expenses. The Company recognized stock-based compensation expense of $12.9 million related to these arrangements for the nine months ended September 30, 2025, consisting of $8.8 million in general and administrative expenses and $4.1 million in research and development expenses. No stock-based compensation expense related to these arrangements was recognized for the three and nine months ended September 30, 2026.

In addition, the Company recognized ACELYRIN Merger transaction costs of $14.7 million in general and administrative expenses for the nine months ended September 30, 2025.

Following the Closing Date, the operating results of ACELYRIN have been included in the Company's consolidated financial statements.

The ACELYRIN Merger is intended to be a reorganization under the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code") Section 368(a). The Merger Agreement outlines the "plan of reorganization" within the meaning of the regulations issued under Internal Revenue Code Section 368(a) and the ACELYRIN Merger is intended to qualify as a tax-free reorganization for U.S. federal and state income tax purposes.

4. Fair Value Measurements

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

The Company's financial instruments consist of Level 1 and Level 2 financial instruments. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy.

Level 1 financial instruments are comprised of money market funds and U.S. Treasury obligations. Level 2 financial instruments are comprised of U.S. Treasury obligations, corporate debt obligations, commercial paper, supranational debt obligations and government development bank obligations. Marketable securities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities.

Recurring Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 47,131	$ —	$ —	$ 47,131
Commercial paper	—	2,984	—	2,984
Marketable securities, current				
U.S. Treasury obligations	173,713	85,775	—	259,488
Corporate debt obligations	—	77,449	—	77,449
Commercial paper	—	36,710	—	36,710
Total assets	$ 220,844	$ 202,918	$ —	$ 423,762

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 81,729	$ —	$ —	$ 81,729
U.S. Treasury obligations	3,971	—	—	3,971
Marketable securities, current				
U.S. Treasury obligations	110,809	37,673	—	148,482
Corporate debt obligations	—	30,743	—	30,743
Commercial paper	—	27,672	—	27,672
Supranational debt obligations	—	7,922	—	7,922
Government development bank obligations	—	4,012	—	4,012
Total assets	$ 196,509	$ 108,022	$ —	$ 304,531

The Company did not hold Level 3 financial instruments measured on a recurring basis and there were no transfers between Level 1 and Level 2 categories during the nine months ended September 30, 2026 and 2025.

Nonrecurring Fair Value Measurements

In June 2026, the Company measured its acquired IPR&D intangible asset at fair value on a nonrecurring basis in connection with an impairment assessment. The fair value measurement was classified within Level 3 of the fair value hierarchy. Based on the assessment, the Company recorded an impairment loss of $41.8 million. No impairment loss was recognized during the three months ended September 30, 2026. See Note 6 for additional information.

5. Marketable Securities

Marketable securities, which are classified as available-for-sale, consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities, current:				
U.S. Treasury obligations	$ 260,016	$ —	$ (528)	$ 259,488
Corporate debt obligations	77,619	1	(171)	77,449
Commercial paper	36,742	—	(32)	36,710
Total marketable securities, current	$ 374,377	$ 1	$ (731)	$ 373,647

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities, current:				
U.S. Treasury obligations	$ 148,352	$ 129	$ —	$ 148,481
Corporate debt obligations	30,720	24	—	30,744
Commercial paper	27,652	20	—	27,672
Supranational debt obligations	7,913	9	—	7,922
Government development bank obligations	4,006	6	—	4,012
Total marketable securities	$ 218,643	$ 188	$ —	$ 218,831

Marketable securities classified as current as of September 30, 2026 and December 31, 2025 had contractual maturities of one year or less from the purchase date.

As of September 30, 2026 and December 31, 2025, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its marketable securities were not significantly impacted. For all marketable securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for expected credit losses was recorded for the three and nine months ended September 30, 2026 and 2025.

6. Intangible Assets

Intangible assets consist of the acquired IPR&D intangible asset related to the lonigutamab product candidate acquired in the ACELYRIN Merger at its estimated fair value of $51.0 million as of the Closing Date. See Note 3 for additional information. The asset is classified as an indefinite-lived intangible asset and, accordingly, is not amortized but is subject to annual impairment testing, or more frequently if events or changes in circumstances indicate that the asset may be impaired.

In May 2026, the Company completed its strategic review of the lonigutamab program and decided to pursue strategic alternatives for the program. This decision represented a triggering event under ASC 350 and required the Company to perform an interim impairment assessment of the acquired IPR&D intangible asset. Based on the results of the impairment assessment, the Company recorded an intangible assets impairment loss of $41.8 million in June 2026, which was recognized as a separate line item within operating expenses in its unaudited condensed consolidated statement of

operations and comprehensive loss. The impairment loss reduced the carrying value of the acquired IPR&D intangible asset to its estimated fair value of $9.1 million as of June 30, 2026.

The fair value of the acquired IPR&D intangible asset was determined using a weighted scenario-based, risk-adjusted discounted cash flow method, which estimates the present value of projected future cash flows attributable to the asset under multiple potential outcomes and applies probability weightings ranging from 10% to 70%. The valuation incorporated significant unobservable inputs and assumptions, including the probability and timing of potential strategic transactions, such as out-licensing arrangements, estimated future cash flows, projected revenues, the probability of technical and regulatory success and a discount rate of 24%.

No impairment loss was recognized for the three months ended September 30, 2026.

7. Balance Sheet Components

Restricted Cash

Restricted cash consists of cash pledged as collateral for standby letters of credit of $1.4 million and $1.3 million as of September 30, 2026 and December 31, 2025, respectively. Substantially all of the restricted cash relates to lease commitments and will remain restricted until the termination or modification of the underlying lease agreements. Restricted cash was classified as non-current in the condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025.

Other Prepaid Expenses and Current Assets

Other prepaid expenses and current assets consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Prepaid subscriptions	$ 2,213	$ 2,088
Interest receivable	1,871	1,343
Tax receivable	1,304	740
Prepaid insurance	1,263	744
Other	1,164	1,825
Total other prepaid expenses and current assets	$ 7,815	$ 6,740

Property and Equipment, Net

Property and equipment, net consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	Estimated Useful Life (in years)	September 30, 2026	December 31, 2025
Leasehold improvements	Shorter of useful life or lease term	$ 18,018	$ 17,655
Laboratory equipment	5	6,345	5,843
Furniture and fixtures	5	1,709	1,709
Computer equipment	5	896	896
Capitalized software	3	75	75
Total property and equipment, gross		27,043	26,178
Less: Accumulated depreciation and amortization		(10,616)	(7,988)
Total property and equipment, net		$ 16,427	$ 18,190

Depreciation and amortization expense was $0.9 million for each of the three months ended September 30, 2026 and 2025, and $2.6 million for each of the nine months ended September 30, 2026 and 2025.

Other Accrued Expenses and Current Liabilities

Other accrued expenses and current liabilities consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Accrued personnel and related expenses	$ 13,781	$ 17,825
Accrued professional services	3,456	4,397
Other	1,094	81
Total other accrued expenses and current liabilities	$ 18,331	$ 22,303

8. Revenue

Kaken Collaboration Agreement

On March 25, 2025 (the “Effective Date”), the Company entered into the Kaken Collaboration Agreement. Under the terms of the Kaken Collaboration Agreement, the Company granted to Kaken an exclusive right to develop, manufacture and commercialize envu for dermatology indications in Japan, with options to expand the license, subject to opt-in payments and certain cost-sharing obligations on the part of Kaken, to include rheumatological and gastrointestinal diseases.

Pursuant to the terms of the Kaken Collaboration Agreement, the Company is responsible for the global development of envu in the dermatology field, and Kaken is responsible for the clinical development, regulatory approvals and commercialization of envu in Japan in dermatology and other indications for which Kaken has exercised its option. Kaken is required to use commercially reasonable efforts to conduct all subsequent development, manufacture and commercialization activities. The Kaken Collaboration Agreement further provides that the Company will retain rights to envu in all other indications and geographies.

In March 2025, Kaken made an upfront, non-refundable payment of $20.0 million to the Company. In addition, Kaken will pay the Company an aggregate of $20.0 million towards global development costs for envu in the dermatology field

through the end of 2026 and thereafter will pay a specified share of development costs applicable to the dermatology field, and for any field for which Kaken exercises its option, subject to Kaken's right to opt out of cost-sharing in certain indications in specified circumstances. In addition, Kaken would pay the Company up to an aggregate of $36.0 million upon the achievement of regulatory milestones and upon Kaken's exercise of its field expansion options for the rheumatology and gastrointestinal fields. In addition, the Company is entitled to receive aggregate payments of up to ¥15.5 billion upon the achievement of commercial milestones, plus tiered royalties at percentages ranging from the low double digits into the twenties on aggregate net sales of envu in Japan.

The Company evaluated the Kaken Collaboration Agreement and concluded it was within the scope of ASC 606. As of the Effective Date, the Company identified four performance obligations: (1) license to develop, manufacture and commercialize envu (the "License Obligation"), (2) development services that support the global development of envu (the "Development Services Obligation"), (3) the manufacture of the clinical supply in Japan (the "Manufacturing Services Obligation") and (4) a material right related to the option for rheumatology disease (the "Material Right Obligation"). The License Obligation was considered functional intellectual property and distinct from other promises under the contract, as Kaken can benefit from the license on its own or together with other readily available resources. The Development Services Obligation and Manufacturing Services Obligation were considered distinct as Kaken could benefit from both of these separately with the license transferred by the Company at the inception of the agreement. The option in the rheumatology field contained a material right because its exercise does not require payment of a fee that is commensurate with the value of the additional license. No material right was assigned to the gastrointestinal field since its estimated fair value did not exceed the exercise price of the option.

The transaction price includes the upfront license fee of $20.0 million, the global development cost reimbursement of $20.0 million in the dermatology field through the end of 2026, the estimated global development cost reimbursement in the dermatology field after 2026 of $1.5 million and an immaterial amount of variable consideration related to the Manufacturing Services Obligation. The Company determined that any variable consideration related to development and regulatory milestones was deemed to be fully constrained at inception and therefore excluded from the initial transaction price due to the high degree of uncertainty and risk associated with these potential payments, and the Company could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

The Company developed the estimated standalone selling prices for the License Obligation and Material Right Obligation primarily based on the probability-weighted value of expected future revenues associated with each underlying license. In developing such estimates, the Company applied judgment in determining the forecasted revenue, taking into consideration the applicable market conditions, the probability of success, and the time needed to develop each indication for which the license relates. The Company developed the estimated standalone selling price for the development services and clinical supply primarily based on the resources to be committed to perform the service.

At inception of the contract, the Company allocated $17.4 million to the License Obligation, $20.8 million to the Development Services Obligation, $3.3 million to the Material Right Obligation and an immaterial amount to the Manufacturing Services Obligation. The License Obligation was satisfied in March 2025 upon transfer of the license to Kaken. For the Development Services Obligation, the Company recognizes revenue over time as Kaken consumes the benefit of such services as they are being performed. The Company measures proportional performance over time for the Development Services Obligation by using an input method based on cost incurred relative to the total estimated cost of the obligation on a quarterly basis. The Company re-evaluates the transaction price as uncertain events are resolved or other changes in circumstances occur as of the end of each reporting period.

The Company recognized license revenue of zero for the three and nine months ended September 30, 2026, and zero and $17.4 million for the three and nine months ended September 30, 2025, respectively, related to the License Obligation. The Company recognized collaboration revenue of $1.9 million and $5.3 million for the three and nine months ended September 30, 2026, respectively, and $2.1 million and $4.7 million for the three and nine months ended September 30, 2025, respectively, related to the Development Services Obligation and Manufacturing Services Obligation. As of September 30, 2026, collaboration revenue receivable was $0.1 million, deferred revenue, current was $6.9 million

and deferred revenue, non-current was zero. As of December 31, 2025, collaboration revenue receivable was less than $0.1 million, deferred revenue, current was $1.5 million and deferred revenue, non-current was $2.6 million. Revenue recognized during the period that was included in deferred revenue at the beginning of the period was $1.8 million and zero for the three months ended September 30, 2026 and 2025, respectively, and $1.5 million and zero for the nine months ended September 30, 2026 and 2025, respectively. The aggregate estimated amount of transaction price that was unsatisfied as of September 30, 2026 was $12.4 million, of which, $9.1 million related to the Development Services Obligation that is expected to be recognized through 2028 as the Company performs its services towards the global development of envu in the dermatology field. The remaining $3.3 million estimated amount of transaction price that was unsatisfied as of September 30, 2026 related to the Material Right Obligation and is deferred until the option is exercised or expires.

Tenet Medicines Purchase Agreement

In January 2024, ACELYRIN entered into an asset purchase agreement ("Purchase Agreement") with Tenet Medicines, Inc. ("Tenet"). In consideration for the assets and other rights Tenet received under the Purchase Agreement, ACELYRIN is entitled to receive development, regulatory and commercial milestone payments of up to $157.5 million in the aggregate based on the achievement of specified milestones, royalties on worldwide net sales, and payments on sublicense income. On December 31, 2025, Climb Bio, Inc. ("Climb Bio"), the parent company of Tenet, filed a complaint in Delaware Superior Court seeking a declaratory judgment that budoprutug is not a "Product" under the Purchase Agreement, and therefore Climb Bio does not owe milestone or royalty payments to the Company under the Purchase Agreement. The Company disputes Climb Bio's interpretation and, in January 2026, issued a notice of material breach to Climb Bio for failing to timely pay a $3.0 million development milestone. The Company intends to seek recovery of the $3.0 million development milestone, as well as any other future milestone or royalty payments, through litigation. The matter remains pending.

9. Related Party Transactions

Foresite Labs Services Agreement

Foresite Labs, LLC ("Foresite Labs") is an affiliate of Foresite Capital Management, a stockholder of the Company. In January 2021, the Company entered into a services agreement with Foresite Labs, which was amended and restated in August 2021 and in December 2023, and expires in December 2026, unless terminated earlier by the parties. Thereafter, on each anniversary of the effective date, the agreement will automatically renew for an additional one-year term, unless terminated earlier by the parties. Foresite Labs provides services to assist the Company in exploring specified immunology genetic targets. The Company recognized $0.1 million and $0.3 million as research and development expenses under the services agreement for the three months ended September 30, 2026 and 2025, respectively. The Company recognized $0.5 million and $0.8 million as research and development expenses under the services agreement for the nine months ended September 30, 2026 and 2025, respectively. There were no accrued expenses under the services agreement as of September 30, 2026 and December 31, 2025.

10. Commitments and Contingent Liabilities

Operating Leases

In August 2022, the Company entered into a lease agreement for 55,000 square feet of office and laboratory space in South San Francisco, California, which commenced in January 2023 and has a contractual termination date in August 2033. The lease agreement includes a renewal option allowing the Company to extend this lease for an additional three years at the prevailing rental rate, which the Company was not reasonably certain to exercise.

In December 2024, the Company entered into a lease agreement for approximately 22,000 square feet of additional office space in South San Francisco, California. The lease has a contractual termination date of December 2026, with the right

to extend the lease for an additional two years subject to certain conditions. The Company determined that, for accounting purposes, the commencement date of the lease is in January 2025 and the lease term ends in December 2026, as it was not reasonably certain that the lease would be extended. As of the commencement date, undiscounted future lease payments totaled $1.9 million and the lease liability was calculated to be $1.8 million, which is equal to the present value of the future lease payments, discounted at an incremental borrowing rate of 7.9%. In April 2026, the Company entered into an amended agreement to extend the lease for an additional two years ending in December 2028. As of the lease modification date, undiscounted future lease payments totaled $2.9 million, and the lease liability was calculated as $2.5 million, which is equal to the present value of future lease payments, discounted at an incremental borrowing rate of 9.3%. The amended agreement has an option to extend the lease for an additional two years subject to certain conditions.

Upon the closing of the ACELYRIN Merger, the Company became the successor to ACELYRIN's rights under ACELYRIN's lease and sublease agreements. In January 2023, ACELYRIN entered into a lease agreement to rent approximately 10,012 square feet of office space in Southern California. The term of the lease is 65 months with an option to extend it for an additional three years. Monthly rent payments are approximately $30 thousand, subject to an annual 3.0% increase. In addition to the base rent, the Company is obligated to pay variable costs related to its share of operating expenses and taxes. In December 2025, the Company entered into an agreement to sublease the entirety of its Southern California leased space through August 24, 2028, the remainder of the lease term. The sublease included the operating lease right-of-use asset and certain property, plant and equipment. Sublease income was immaterial for the three and nine months ended September 30, 2026. In April 2026, the Company delivered a notice of termination to the sublessee, and the sublease was terminated in April 2026.

In July 2023, ACELYRIN entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco, California. The term of the lease is 60 months with an option to extend it for an additional five years. Monthly base rent payments are approximately $0.2 million, subject to an annual 3.5% increase. In addition to the base rent, the Company is obligated to pay variable costs related to its share of operating expenses and taxes. In February 2025, ACELYRIN entered into an agreement to sublease the entirety of its South San Francisco leased space through October 2029, the remainder of the lease term. The sublease included the operating lease right-of-use asset and certain property, plant and equipment. Sublease income was immaterial for the three and nine months ended September 30, 2026.

The components of lease costs were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 1,261	$ 1,377	$ 3,825	$ 3,682
Variable lease costs	407	336	1,088	993
Total lease costs	$ 1,668	$ 1,713	$ 4,913	$ 4,675

Supplemental cash flow information related to the operating leases was as follows (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Cash payments included in the measurement of operating lease liabilities	$ 6,429	$ 5,160

Weighted-average remaining lease term and incremental borrowing rate for the operating leases were as follows:

	September 30, 2026	December 31, 2025
Weighted-average remaining lease term (years)	6.0	6.8
Weighted-average incremental borrowing rate	11.5 %	11.6 %

Future minimum lease payments under non-cancelable leases as of September 30, 2026, were as detailed below (in thousands):

2026 (remainder of the year)	$ 2,145
2027	8,702
2028	8,762
2029	7,205
2030	5,848
Thereafter	16,009
Total undiscounted lease payments	48,671
Less: Imputed interest	(13,365)
Total operating lease liabilities	$ 35,306

FronThera Contingent Consideration

In March 2021, the Company entered into a stock purchase agreement to acquire FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC (the "FronThera Acquisition"), which was accounted for as an asset acquisition. Under the stock purchase agreement, the Company is obligated to pay contingent consideration of up to an aggregate of $120.0 million based on the achievement of specified clinical and approval milestones, consisting of up to $70.0 million for clinical milestones, and of up to $50.0 million for approval milestones, including receipt of first commercialization approval in the United States or certain other jurisdictions, all related to technology acquired under the agreement. As of September 30, 2026, the Company had achieved and paid two clinical milestones totaling $60.0 million. No additional milestones were achieved or were probable of being achieved as of September 30, 2026.

License and Commercialization Agreement with Pierre Fabre

Upon the closing of the ACELYRIN Merger, the Company became the successor to ACELYRIN's rights and obligations under the March 25, 2021 license and commercialization agreement with Pierre Fabre Medicament SAS ("Pierre Fabre"), as amended (the "Pierre Fabre Agreement"), through which ACELYRIN received certain exclusive worldwide licenses with the right to sublicense certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a "PF Licensed Product"). The Pierre Fabre Agreement prohibits the Company from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

The Company is obligated to (i) make payments of up to $100.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event the Company enters into a sublicense with a third party, the Company must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense relates to.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the

bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if the Company or any of its affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. The Company may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

No milestones were achieved or were probable of being achieved as of September 30, 2026.

Purchase Commitments

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, clinical research organizations ("CROs"), contract manufacturing organizations ("CMOs") and clinical trial sites. Upon the closing of the ACELYRIN Merger, the Company became the successor to contracts with non-cancellable commitments under ACELYRIN contracts. The total value of non-cancellable purchase commitments under contracts was $0.3 million as of September 30, 2026. This presentation of non-cancellable purchase commitments does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of its engagements.

Legal Contingencies

From time to time, the Company has and may become involved in legal proceedings arising in the ordinary course of business, any or all of which could have a material adverse impact on the Company, including its financial position. The outcomes of legal proceedings are not within the Company's complete control and may not be known for prolonged periods of time. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Legal costs related to these matters, including attorney fees, are expensed as incurred and are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California (the "Court"). On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-FMO-MAA), naming ACELYRIN and then-current and former executive officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial evaluating izokibep in hidradenitis suppurativa. The original complaint was filed following ACELYRIN's announcement of the week 16 results from the Part B portion of such Phase 2b trial. The amended complaint seeks damages and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the Court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the Court, with leave to amend, in January 2026. On February 5, 2026, the plaintiffs filed a second amended complaint, which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the Court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or its officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of this lawsuit is necessarily uncertain. The Company could be forced to expend significant resources in the defense against this and any other related lawsuits and the Company may not prevail. The Company currently is not able to estimate the possible loss to the Company from this lawsuit, as this lawsuit is currently at an early stage, and such amounts could be material to the Company's financial statements even if the Company prevails in the defense against this lawsuit. The Company cannot be certain how long it may take to resolve this lawsuit or the possible amount of any damages that the Company may be required to pay. As of September 30, 2026, the Company did not consider any payment to be probable or reasonably estimable and had not accrued for any potential liability relating to this lawsuit.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was, serving in such capacity. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2026 and December 31, 2025, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

11. Stockholders' Equity

As of September 30, 2026, the Company was authorized to issue up to 50,000,000 shares of preferred stock, 492,815,092 shares of voting common stock and 7,184,908 shares of non-voting common stock, all with a par value of $0.0001 per share. As of September 30, 2026, there were no shares of preferred stock issued or outstanding, 129,680,481 shares of voting common stock issued and outstanding and no shares of non-voting common stock issued or outstanding. During the nine months ended September 30, 2026, 5,622,408 shares of non-voting common stock were converted into voting common stock.

The holders of voting and non-voting common stock have the same rights except that non-voting common stock does not have voting rights, except as may be required by law. Each holder of non-voting common stock has a right to convert each share of non-voting common stock to one share of voting common stock subject to the following limitations. At any time following the Company's registration of any class of equity securities under the Exchange Act, the holders of shares of non-voting common stock may not convert a number of shares of non-voting common stock into shares of voting common stock in excess of that number of shares of non-voting common stock which would cause the holder thereof to beneficially own (for purposes of Section 13(d) of the Exchange Act), in excess of 4.99% of the total number of issued and outstanding shares of voting common stock. Such maximum percentage may be increased or decreased to such other percentage as any holder of outstanding shares of non-voting common stock may designate in writing (in the case of an increase upon 61 days' prior written notice).

Common stock reserved for issuance consisted of the following as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Stock options issued and outstanding	21,203,723	20,353,098
RSUs issued and outstanding	2,605,582	2,527,377
Shares available for grant under the 2024 Equity Incentive Plan	1,013,783	597,112
Shares available for grant under the 2024 Employee Stock Purchase Plan	1,599,251	805,334
Shares available for grant under the ACELYRIN, Inc. 2023 Equity Incentive Plan	6,050,194	6,585,521
Shares available for grant under the 2024 Performance Option Plan	202,314	200,208
Total	32,674,847	31,068,650

Common Stock Issued to Executives

In February 2021, the Company issued 100,532 shares of restricted common stock to two executives at a purchase price of $0.94 per share. The shares vested over a four-year period with a one-year cliff vesting. While the shares were unvested, the holders had voting and dividends rights and the Company had the right to repurchase unvested shares of common stock at the price paid by the holder in the event of termination of the holder's continuous status as a service provider. The Company estimated the fair value of the restricted stock awards based on the fair value of common stock at the grant dates. The expense was recognized ratably over the vesting terms. The restricted common stock fully vested as of March 31,

2025. The Company recognized less than $0.1 million of stock-based compensation expense for the three and nine months ended September 30, 2025.

12. Stock-Based Compensation

2021 Stock Plan

In February 2021, the Company adopted the 2021 Stock Plan (the "2021 Plan"), which provided for stock awards to eligible employees, directors and consultants of the Company. Awards issuable under the 2021 Plan included incentive stock options ("ISOs"), non-statutory stock options ("NSOs"), RSUs and stock grants. Subsequent to the adoption of the 2024 Equity Incentive Plan (the "2024 EIP") in June 2024, described below, no additional shares were available for issuance under the 2021 Plan, and any stock options granted under the 2021 Plan that were subsequently forfeited would be made available for issuance under the 2024 EIP.

The terms of the 2021 Plan permit option holders to exercise stock options before their stock options are vested. The shares of common stock granted upon early exercise that have not yet vested are subject to repurchase by the Company in the event of termination of the holder's continuous status as a service provider, at the price paid by the holder.

2024 Performance Option Plan

In May 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Performance Option Plan (the "2024 POP"). The Company reserved 1,880,680 shares of common stock issuable under the 2024 POP. The 2024 POP permits grants of ISOs, NSOs and restricted stock awards to the Company's employees, directors and consultants.

In May 2024, the Company granted NSOs to employees to purchase 1,880,680 shares of common stock at an exercise price of $10.19 under the 2024 POP. Stock options generally vest on the date when the Company meets certain common stock public market price specified targets after the end of the IPO lock-up period, subject to continuous service through each respective vest date. The price targets are calculated based on the volume weighted-average price per share over 30 consecutive trading dates, in accordance with the grant terms. The unvested awards will expire if it is determined that the vesting conditions have not been met during the applicable six-year performance period. The service condition includes monthly vesting over 36 months from the vesting commencement date and the employee's continuous service with the Company through each such monthly vesting date. The terms of the 2024 POP permit option holders to exercise stock options before their stock options are vested, if the market condition has been met.

2024 Equity Incentive Plan

In June 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 EIP, which became effective on June 27, 2024, upon execution of the underwriting agreement related to the Company's IPO. The Company reserved 7,800,000 new shares of common stock for issuance under the 2024 EIP. In addition, up to 6,829,339 shares subject to awards under the 2021 Plan that terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, were authorized to be added to the 2024 EIP. The 2024 EIP also provides that the number of shares initially reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2025 through January 1, 2034, by an amount equal to 5% of the outstanding number of shares of the Company's common stock as of the last day of the immediately preceding fiscal year, or such lesser number of shares as determined by the board of directors prior to the applicable January 1. Pursuant to this evergreen provision, the Company increased the number of shares reserved under the 2024 EIP by 5,235,338 on January 1, 2026. No more than 43,888,017 shares of common stock may be issued under the 2024 EIP.

The 2024 EIP allows the Company to grant equity awards to its officers, employees, directors and consultants. The 2024 EIP provides for the grant of ISOs, NSOs, restricted stock awards, RSUs, stock appreciation rights, performance awards

and other stock-based awards. Stock options under the 2024 EIP may be granted for periods of up to 10 years at exercise prices no less than the fair market value of common stock on the date of grant; provided, however, that the exercise price of an ISO granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. Stock options and RSUs granted under the 2024 EIP generally vest over four years. The grant date fair market value of all awards made under the 2024 EIP and all cash compensation paid by the Company to any non-employee director for services as a director in any fiscal year may not exceed $750,000, increased to $1,000,000 in the fiscal year of their initial service as a non-employee director. The terms of the 2024 EIP do not permit option holders to exercise stock options before their stock options are vested.

ACELYRIN Plans

Pursuant to the Merger Agreement, the Company assumed certain stock options, RSUs and performance RSUs outstanding under the ACELYRIN, Inc. 2020 Stock Option and Grant Plan, as amended (the "ACELYRIN 2020 Plan"), the ValenzaBio, Inc. Stock Plan (the "ValenzaBio Plan") and the ACELYRIN, Inc. 2023 Equity Incentive Plan (the "ACELYRIN 2023 Plan" and, together with the ACELYRIN 2020 Plan and the ValenzaBio Plan, the "ACELYRIN Plans"). In connection with the closing of the ACELYRIN Merger, the Company also assumed the ACELYRIN 2023 Plan, which, as modified in connection with such assumption, permits equity awards to be issued to the extent permissible under applicable law and Nasdaq listing rules.

Stock options that were outstanding under the ACELYRIN Plans immediately prior to the Closing Date were assumed by the Company and converted into stock options to purchase the Company's common stock. RSUs that were outstanding and unvested immediately prior to the Closing Date were assumed by the Company and converted into the Company's RSU awards. Performance RSUs outstanding and unvested immediately prior to the Closing Date were converted into the Company's RSU awards subject only to a service vesting condition.

Stock Option Activity

The following table summarizes the Company's stock option activity, excluding under the 2024 POP, for the nine months ended September 30, 2026 and includes early exercised shares as part of stock options exercised:

	Stock Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	18,672,626	$ 8.56	6.7	$ 44,015
Granted	5,121,953	$ 25.64		
Exercised	(3,749,825)	$ 11.16		$ 2,978
Forfeited or expired	(519,397)	$ 20.80		
Outstanding, vested and expected to vest as of September 30, 2026	19,525,357	$ 12.21	7.8	$ 20,075
Exercisable as of September 30, 2026	9,540,660	$ 8.53	6.8	$ 8,222

Total exercisable shares of 9,540,660 as of September 30, 2026 included 1,182,986 unvested shares that were early exercisable under the 2021 Plan. The total fair value of stock options vested during the nine months ended September 30, 2026 and 2025 was $19.7 million and $22.1 million, respectively.

The following table summarizes the Company's stock option activity under the 2024 POP for the nine months ended September 30, 2026:

	Stock Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	1,680,472	$ 10.19	8.3	$ —
Granted	—	$ —		
Forfeited or expired	(2,106)	$ 10.19		
Outstanding, vested and expected to vest as of September 30, 2026	1,678,366	$ 10.19	7.5	$ —
Exercisable as of September 30, 2026	—	$ —	—	$ —

Valuation of Stock Options Granted

The weighted-average grant date fair value of stock options granted for the nine months ended September 30, 2026 and 2025 was $20.09 and $3.72 per stock option, respectively.

The fair value of stock options granted for the nine months ended September 30, 2026 and 2025 was estimated using the Black-Scholes option pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2026	2025
Expected term (in years)	5.27 - 6.06	5.23 - 6.08
Volatility	78.55% - 96.71%	98.84% - 104.32%
Risk-free interest rate	3.81% - 4.80%	3.69% - 4.65%
Dividend yield	0.00%	0.00%

Expected Term

The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the stock options' vesting terms and contractual terms, as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

Expected Volatility

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history of its common stock. The Company will continue to use industry peers in determining historical stock price volatility until sufficient historical data of its common stock becomes available.

Risk-Free Interest Rate

The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

Dividends

The Company has not paid any cash dividends on common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

Valuation of Stock Options Granted under the 2024 POP

Stock options granted under the 2024 POP vest based on service, market and performance conditions (the occurrence of the IPO or a change of control) and are classified as equity financial instruments. At the grant date, the fair value of stock options granted under the 2024 POP was estimated using a Monte Carlo simulation model, which uses a distribution of potential outcomes on a monthly basis over the vesting period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price thresholds, including the Company's expected common stock price, expected volatility, risk-free rate and expected term. The Company used the following assumptions to estimate the fair value at the grant date in May 2024: common stock fair value of $12.06, vesting term of 6.0 years, volatility of 122.00%, and risk-free rate of 4.38%. The estimates of fair value are uncertain and changes in any of the estimated inputs could have resulted in significant adjustments to the fair value.

The Company's estimated fair value of stock options issued under the 2024 POP of $18.0 million is recognized using graded vesting from July 1, 2024, the closing of the IPO, when the performance condition was met, over the longer of (i) the explicit service period of the service condition of 36 months or (ii) the derived service period between 1.4 years to 2.1 years, as determined for each graded vesting tranche.

Early Exercise of Employee Stock Options

Proceeds from the early exercise of stock options in excess of par value are recorded as a share repurchase liability, and as the underlying shares vest, these proceeds are recognized in additional paid-in capital in the consolidated balance sheets. The share repurchase liability related to unvested shares was $0.1 million as of both September 30, 2026 and December 31, 2025, and was classified within other liabilities, non-current in the condensed consolidated balance sheets.

The following table summarizes the Company's early exercised shares activity for the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Exercise Price Per Share
Unvested as of December 31, 2025	13,681	$ 9.01
Vested	(7,824)	$ 9.10
Unvested as of September 30, 2026	5,857	$ 8.88

2024 Employee Stock Purchase Plan

In June 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective on June 28, 2024, upon execution of the underwriting agreement related to the Company's IPO. The Company initially reserved 650,000 shares of common stock for issuance under the 2024 ESPP. The number of shares of common stock reserved for issuance under the 2024 ESPP will be automatically increased each year for ten calendar years beginning on January 1, 2025 through January 1, 2034, by the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 1,950,000 shares; provided that before the date of any such increase, the board of directors may determine that such increase will be less than the amount in (i) and (ii) above. Pursuant to this evergreen provision, the Company increased the number of shares reserved under the 2024 ESPP by 1,047,067 on January 1, 2026.

The 2024 ESPP allows an eligible employee to purchase shares of common stock at an amount equal to 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at each applicable purchase date during an offering period as established by the board of directors. The first purchase period commenced on January 24, 2025 and ended on May 20, 2025. During the nine months ended September 30, 2026 and 2025, 253,150 and 184,633 shares of common stock were purchased under the 2024 ESPP, respectively.

The following table summarizes the Black-Scholes option pricing model used in estimating the fair value of the stock purchase rights under the 2024 ESPP for the nine months ended September 30, 2026:

	Nine Months Ended September 30, 2026
Expected term (in years)	0.49 - 0.50
Volatility	67.54% - 126.68%
Risk-free interest rate	3.75% - 3.78%
Dividend yield	0.00%

Restricted Stock Units

The following table summarizes the Company's unvested RSUs activity for the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested as of December 31, 2025	2,527,377	$ 4.01
RSUs granted	913,406	$ 25.15
RSUs released	(673,233)	$ 4.40
RSUs forfeited	(161,968)	$ 8.35
Unvested as of September 30, 2026	2,605,582	$ 11.05

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense recognized in the Company's unaudited condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 8,494	$ 5,773	$ 24,489	$ 16,717
General and administrative	5,792	4,014	16,409	18,700
Total stock-based compensation expense	$ 14,286	$ 9,787	$ 40,898	$ 35,417

The following table summarizes stock-based compensation expense recognized in the Company's unaudited condensed consolidated statements of operations and comprehensive loss by award type for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	$ 11,395	$ 7,979	$ 33,539	$ 28,771
RSUs	2,477	1,542	6,267	5,939
ESPP	414	266	1,092	701
Restricted stock awards	—	—	—	6
Total stock-based compensation expense	$ 14,286	$ 9,787	$ 40,898	$ 35,417

Stock-based compensation expense related to non-employee awards was $0.7 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and was $1.4 million and $0.5 million for the nine months ended September 30, 2026 and 2025, respectively. Stock-based compensation expense related to the 2024 POP was $0.4 million and $1.5 million for the three months ended September 30, 2026 and 2025, respectively, and $2.6 million and $5.7 million for the nine months ended September 30, 2026 and 2025, respectively. Stock-based compensation expense included $2.1 million and $12.9 million in severance costs related to the ACELYRIN Merger for the three and nine months ended September 30, 2025, respectively. See Note 3 for additional information.

As of September 30, 2026, unrecognized stock-based compensation expense for all stock awards was $142.4 million, which the Company expects to recognize over a weighted-average period of 2.7 years.

13. Employee Benefit Plans

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. In November 2025, the Company's board of directors approved a Company match of 100% of participating employee's deferral contribution up to 3% of eligible compensation and a 50% match of participating employees' deferral contribution from 3% to 5% of eligible compensation, effective from January 1, 2026. The Company contributed $0.4 million and $1.8 million to the 401(k) plan for the three and nine months ended September 30, 2026, respectively.

14. Net Loss Per Share Attributable to Common Stockholders

The following table presents the computation of the basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2026 and 2025 (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	$ (94,881)	$ (110,752)	$ (330,155)	$ (150,394)
Denominator:				
Weighted-average shares of common stock outstanding	129,300,405	104,150,531	127,369,436	78,554,685
Less: Weighted-average shares of common stock subject to repurchase	(6,556)	(41,288)	(9,042)	(83,278)
Weighted-average shares of common stock outstanding, basic and diluted	129,293,849	104,109,243	127,360,394	78,471,407
Net loss per share attributable to common stockholders, basic and diluted	$ (0.73)	$ (1.06)	$ (2.59)	$ (1.92)

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been antidilutive:

	Three and Nine Months Ended September 30,	
	2026	2025
Stock options issued and outstanding	21,203,723	20,090,359
RSUs issued and outstanding	2,605,582	2,670,905
Common stock issuable under the 2024 ESPP	105,557	241,027
Early exercised stock options and unvested restricted common stock	5,857	20,878
Total	23,920,719	23,023,169

15. Segment Reporting

For purposes of evaluating performance and allocating resources, the Company's CODM, its Chief Executive Officer, regularly reviews consolidated net loss as reported in the Company's consolidated statements of operations and comprehensive loss as compared to budget. The measure of segment assets is reported in the consolidated balance sheets as total consolidated assets.

In addition to the significant expense categories included within consolidated net loss presented in the Company's condensed consolidated statements of operations and comprehensive loss, see below for disaggregated amounts that comprise research and development expenses for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
License revenue	$ —	$ —	$ —	$ 17,389
Collaboration revenue	1,907	2,066	5,310	4,732
Total revenue	1,907	2,066	5,310	22,121
Operating expenses:				
Research and development expenses				
External costs				
CROs, CMOs and clinical trials	33,474	56,457	114,839	187,618
Professional consulting services	8,237	8,227	23,662	22,047
Other research and development costs	5,740	1,617	11,496	6,908
Internal costs				
Personnel-related costs	27,220	24,854	80,497	69,334
Facilities and overhead costs	6,121	6,681	17,175	17,306
Total research and development expense	80,792	97,836	247,669	303,213
General and administrative expenses	20,191	19,522	62,157	76,267
Intangible assets impairment loss	—	—	41,824	—
Total operating expenses	100,983	117,358	351,650	379,480
Loss from operations	(99,076)	(115,292)	(346,340)	(357,359)
Total other income (expense), net	4,195	4,540	14,428	198,404
Net loss before income taxes	(94,881)	(110,752)	(331,912)	(158,955)
Income tax benefit	—	—	1,757	8,561
Net loss	$ (94,881)	$ (110,752)	$ (330,155)	$ (150,394)

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 and the unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q in conjunction with the financial statements and related notes thereto as of and for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report on Form 10-K filed with the SEC on March 19, 2026. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A "Risk Factors" in this Quarterly Report on Form 10-Q. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words "allumer"—French for illuminate—and "immunis"—Latin for the immune system.

We are a clinical stage biopharmaceutical company with an initial focus on developing our two Tyrosine Kinase 2 ("TYK2") inhibitors: envu, a second-generation inhibitor that we are developing to maximize target inhibition and optimize tolerability, and A-005, a central nervous system ("CNS") penetrant molecule. We completed the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials of envu in patients with PsO, and reported positive topline results in the first quarter of 2026. We plan to submit an NDA for envu in PsO to the U.S. Food and Drug Administration ("FDA") by the end of 2026. We are also evaluating envu in an ongoing Phase 2 open-label extension ("OLE") clinical trial and the Phase 3 ONWARD3 long-term extension ("LTE") clinical trial in patients with PsO. We reported data from the ongoing ONWARD3 LTE trial in the second half of 2026. In September 2026, we reported topline results from Part A of our Phase 2b clinical trial evaluating envu in patients with systemic lupus erythematosus ("SLE"). In April 2024, we initiated our Phase 1 program of A-005 in healthy volunteers and reported Phase 1 results in December 2024. We plan to initiate a Phase 2 biomarker trial of A-005 in Parkinson's disease in 2027. In addition, in connection with the ACELYRIN Merger, we acquired lonigutamab, a subcutaneously delivered monoclonal antibody targeting IGF-1R for the potential treatment of TED. In May 2026, we completed our strategic review of the lonigutamab program and decided to pursue strategic alternatives for the program.

Since our inception, we have devoted substantially all of our efforts to organizing our company, hiring personnel, business planning, acquiring and developing our product candidates, performing research and development, conducting preclinical studies and clinical trials, establishing and protecting our intellectual property portfolio, raising capital, integrating the acquired ACELYRIN business and personnel, and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our expanded organization following the ACELYRIN Merger. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates. There can be no assurance that we will ever achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis.

We have incurred significant operating losses and negative cash flows since our inception. Net loss was $94.9 million and $110.8 million for the three months ended September 30, 2026 and 2025, respectively, and $330.2 million and $150.4 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $1,232.0 million.

Substantially all of our net losses have resulted from costs incurred in connection with our research and development efforts, including acquisitions of in-process research and development assets, and, to a lesser extent, from general and

administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our preclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under our existing or future license agreements. We have incurred and will continue to incur costs associated with operating as a public company, including significant legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance costs, investor and public relations costs, and other expenses.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, particularly if and as we:

- continue to progress the development of our product candidates in multiple clinical trials;
- prepare to submit an NDA for envu in PsO by the end of 2026, including as we conduct activities that are required to complete our planned NDA submission;
- explore additional indications for our existing product candidates;
- obtain, maintain, expand and protect our intellectual property rights;
- make royalty, milestone or other payments under the FronThera Acquisition, the Pierre Fabre Agreement and any future license or collaboration agreements;
- seek to identify, acquire or in-license new technologies or product candidates;
- seek regulatory and marketing approvals for any of our product candidates;
- procure manufacturing and supply chain capacity for our product candidates, including commercial manufacturing readiness and scale-up;
- experience any delays, challenges or other issues associated with the clinical development and regulatory approvals of our product candidates;
- hire additional personnel to support our product research and development, clinical execution and planned future commercialization efforts, as well as to support our operating as a public company;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- operate as a public company.

We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

We do not currently own or operate any manufacturing facility. We rely on CMOs to produce our product candidates in accordance with the FDA's current Good Manufacturing Practices ("cGMP") regulations for use in our clinical studies. We have entered into development and manufacturing agreements with various CMOs relating to process development, manufacturing of drug substance and drug product, and quality testing of our product candidates. We expect to rely on our CMOs in the future for the manufacturing of our product candidates in order to expedite readiness for future clinical trials. Most of these CMOs have demonstrated capability in preparation of materials for commercialization. Additionally, we may decide to build our own manufacturing facility in the future to provide us with greater flexibility and control over our clinical or commercial manufacturing needs.

Given our stage of development, we do not yet have a fully established marketing or sales organization or commercial infrastructure; however, we have begun building foundational capabilities and intend to continue expanding the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development and regulatory approval. We expect to spend a significant amount in commercial development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates.

Controlled Equity Offering℠

On March 18, 2026, we entered into the Sales Agreement with Cantor as sales agent, pursuant to which we may offer and sell, from time to time through Cantor, at our option, the ATM Shares. The ATM Shares include shares of our common stock having an aggregate offering price of up to $300.0 million. The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq Global Select Market. We agreed to pay Cantor a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by Cantor. As of the date of issuance of these financial statements, no ATM Shares have been sold under the Sales Agreement.

Public Offering of Common Stock

On January 7, 2026, we entered into the Underwriting Agreement with the Underwriters, relating to the issuance and sale in a public offering of 17,650,000 shares of our common stock at a price of $17.00 per share. In addition, we granted the Underwriters an option, exercisable for 30 days, to purchase up to 2,647,500 additional shares of common stock at the public offering price, less the underwriting discounts and commissions, which was exercised in full on January 8, 2026. On January 9, 2026, the offering closed and we received net proceeds of $324.4 million, after deducting underwriting discounts and commissions.

ACELYRIN Merger

On February 6, 2025, we entered into a Merger Agreement with ACELYRIN and Merger Sub, a Delaware corporation and a direct wholly owned subsidiary. The Merger Agreement was approved by the disinterested directors on our board of directors and the board of directors of ACELYRIN and was approved by the stockholders of each company on May 13, 2025. On May 21, 2025, we completed the ACELYRIN Merger for a purchase consideration of $238.1 million that included the issuance of 48,653,549 shares of our common stock and the fair value of replacement awards attributable to pre-combination services, to acquire net assets with a fair value of $426.0 million. See Note 3 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Our results of operations include the accounts of our wholly owned subsidiary ACELYRIN and its wholly owned subsidiary, WH2, LLC, from the closing of the ACELYRIN Merger. WH2, LLC had no operations or balances from the

closing of the ACELYRIN Merger through its dissolution in September 2026. Our results of operations also included the accounts of Merger Sub from its incorporation in January 2025 until the ACELYRIN Merger. Accordingly, the comparability of our results of operations for the periods presented below was impacted by the timing of the ACELYRIN Merger.

Macroeconomic Trends

Our business and results of operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges and uncertainty in the markets, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (for example, related to the evolving U.S. and ex-U.S. tariff landscape). Further, the United States and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods. For example, in April 2025 the U.S. government imposed a 10% baseline global tariff and subsequently imposed higher "reciprocal" tariffs on numerous territories, including European Union ("EU") member states and South Korea. In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act did not authorize the President to impose tariffs, invalidating tariffs imposed pursuant to that authority. Following the Supreme Court's decision, the Trump Administration imposed a temporary global tariff under Section 122 of the Trade Act of 1974, which has since expired. Other tariffs imposed under separate authorities, including those under Section 232 of the Trade Expansion Act of 1962 on certain pharmaceutical ingredients, remain in effect, and the Trump Administration has continued to pursue additional tariff measures under other trade authorities. The U.S. trade and tariff landscape continues to evolve, and the scope, timing and duration of existing and potential tariffs remain uncertain. Our operations and financial results could be adversely impacted given the volatility and uncertainty regarding U.S. and foreign government trade policies and by global volatility and general market disruption resulting from geopolitical tensions, such as the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the United States, Israel and Iran. In particular, disruptions to global energy markets, fuel prices, transportation networks and supply chains could disrupt or otherwise negatively impact our supply chain and increase our costs. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. To date, the macroeconomic trends discussed above have not had a material adverse impact on our business, financial condition or results of operations. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

Components of Results of Operations

Revenue

Our license and collaboration revenue relates to the Kaken Collaboration Agreement, which we entered into on March 25, 2025. Under the terms of the Kaken Collaboration Agreement, we granted to Kaken an exclusive right to develop, manufacture and commercialize envu for dermatology indications in Japan, with options to expand the license, subject to opt-in payments and certain cost-sharing obligations on the part of Kaken, to include rheumatological and gastrointestinal diseases.

Pursuant to the terms of the Kaken Collaboration Agreement, we are responsible for the global development of envu in the dermatology field, and Kaken is responsible for the clinical development, regulatory approvals and commercialization of envu in Japan in dermatology and other indications for which Kaken has exercised its option. Kaken is required to use commercially reasonable efforts to conduct all subsequent development, manufacture and commercialization activities. The Kaken Collaboration Agreement further provides that we will retain rights to envu in all other indications and geographies.

In March 2025, Kaken made an upfront, non-refundable payment of $20.0 million to us. In addition, Kaken will pay us an aggregate of $20.0 million towards global development costs of envu in the dermatology field through the end of 2026 and thereafter will pay a specified share of development costs applicable to the dermatology field, and for any field for

which Kaken exercises its option, subject to Kaken's right to opt out of cost-sharing in certain indications in specified circumstances. In addition, Kaken would pay us up to an aggregate of $36.0 million upon the achievement of regulatory milestones and upon Kaken's exercise of its field expansion options for the rheumatology and gastrointestinal fields. In addition, we are entitled to receive aggregate payments of up to ¥15.5 billion upon the achievement of commercial milestones, plus tiered royalties at percentages ranging from the low double digits into the twenties on aggregate net sales of envu in Japan.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) general and administrative expenses and (iii) intangible assets impairment loss.

Research and Development Expenses

Research and development expenses consist of external and internal costs primarily related to acquiring and developing our research pipeline and technologies and clinical development of our product candidates.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- expenses incurred in connection with the discovery and preclinical development of our pipeline programs;
- costs incurred in connection with the clinical development of our product candidates, including under agreements with CROs, CMOs and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, annual bonuses, benefits, travel and meals expenses and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software licenses, computer supplies and accessories and other miscellaneous expenses.

We have acquired and may continue to acquire the rights to develop and commercialize new product candidates. Upfront payments related to acquired IPR&D assets are recognized as expenses when we determine that the assets acquired do not have alternative future uses. Milestone payments are accrued and expensed when the achievement of the milestone is probable up to the point of regulatory approval and, absent obtaining such approval, have no alternative future use. Milestone payments made after a product's regulatory approval will be capitalized and amortized over the remaining useful life of the related product.

We expense research and development costs as incurred. Acquired IPR&D intangible assets recognized in a business combination are recorded as indefinite-lived intangible assets and are subject to impairment testing. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as research and development prepaid expenses in our consolidated balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or services are performed. Since our inception and through September 30, 2026, our external research and development expenses were primarily related to the discovery and advancement of programs under our TYK2 platform, including our two most advanced product candidates, envu and

A-005. We use internal resources primarily for managing our research, process development, manufacturing and clinical development activities. In particular, with respect to internal costs, we deploy our personnel across all of our research and development activities as our employees work across multiple programs, and therefore the costs cannot be allocated to a particular product candidate or research program.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through clinical trials, pursue regulatory approval of our product candidates, build our operational and commercial capabilities for marketing our products, if approved, and expand our pipeline of product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is time-consuming, expensive and uncertain. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, clinical data, investment in our clinical programs, competition, manufacturability and commercial viability. It is possible that we may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration or cost to complete our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved by the FDA and other comparable foreign regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the costs and timing of manufacturing of our product candidates;
- the amount and timing of any milestone payment due under our FronThera Acquisition, Pierre Fabre Agreement, and any future license or collaboration agreements;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants;
- patient drop-out or discontinuation rates;
- additional safety monitoring if requested by regulatory authorities;
- the phase of development of our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities including the FDA and comparable foreign regulatory authorities;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and

- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

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

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel-related costs, legal and consulting services, including those relating to intellectual property and corporate matters, marketing expenses and allocated facilities and other overhead costs, including software licenses, computer supplies, insurance and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, travel and meal expenses and stock-based compensation expense for our general and administrative personnel.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including preparing for potential commercialization of our product candidates. We also expect to continue incurring costs associated with being a public company, including costs related to accounting, audit, legal, consulting fees, regulatory and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements, additional director and officer insurance costs, and investor and public relations costs.

Other Income (Expense)

Other income (expense) consists primarily of interest income, including amortization of premiums and accretion of discounts on marketable securities and the gain on bargain purchase.

At the closing of the ACELYRIN Merger in May 2025, we recognized a gain on bargain purchase which represents the excess of fair value of net assets acquired in the ACELYRIN Merger over the purchase consideration on the Closing Date. The gain on bargain purchase was recognized as other income in the condensed consolidated statements of operations and comprehensive loss as of the Closing Date of the ACELYRIN Merger. See Note 3 to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Income Tax Benefit

Income tax benefit consists primarily of the tax effects of changes in our deferred tax assets and liabilities and related valuation allowance, including tax effects associated with our acquired IPR&D intangible asset and the ACELYRIN Merger.

Results of Operations

The following tables summarize our results of operations for the three and nine months ended September 30, 2026 and 2025 (dollars in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
Collaboration revenue	$ 1,907	$ 2,066	$ (159)	(8)%
Total revenue	1,907	2,066	(159)	(8)%
Operating expenses:				
Research and development expenses	80,792	97,836	(17,044)	(17)%
General and administrative expenses	20,191	19,522	669	3 %
Total operating expenses	100,983	117,358	(16,375)	(14)%
Loss from operations	(99,076)	(115,292)	16,216	(14)%
Other income (expense):				
Interest income	4,304	4,594	(290)	(6)%
Other income (expenses), net	(109)	(54)	(55)	102 %
Total other income (expense), net	4,195	4,540	(345)	(8)%
Net loss before income taxes	(94,881)	(110,752)	15,871	(14)%
Income tax benefit	—	—	—	*
Net loss	$ (94,881)	$ (110,752)	$ 15,871	(14)%

* not meaningful

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
License revenue	$ —	$ 17,389	$ (17,389)	*
Collaboration revenue	5,310	4,732	578	12 %
Total revenue	5,310	22,121	(16,811)	(76)%
Operating expenses:				
Research and development expenses	247,669	303,213	(55,544)	(18)%
General and administrative expenses	62,157	76,267	(14,110)	(19)%
Intangible assets impairment loss	41,824	—	41,824	*
Total operating expenses	351,650	379,480	(27,830)	(7)%
Loss from operations	(346,340)	(357,359)	11,019	(3)%
Other income (expense):				
Gain on bargain purchase	—	187,907	(187,907)	*
Interest income	14,601	10,633	3,968	37 %
Other income (expenses), net	(173)	(136)	(37)	27 %
Total other income (expense), net	14,428	198,404	(183,976)	*
Net loss before income taxes	(331,912)	(158,955)	(172,957)	109 %
Income tax benefit	1,757	8,561	(6,804)	(79)%
Net loss	$ (330,155)	$ (150,394)	$ (179,761)	120 %

* not meaningful

Revenue

We recognized license revenue of zero for each of the three months ended September 30, 2026 and 2025, and collaboration revenue of $1.9 million and $2.1 million for the three months ended September 30, 2026 and 2025, respectively, related to the Kaken Collaboration Agreement. We recognized license revenue of zero and $17.4 million for the nine months ended September 30, 2026 and 2025, respectively, and collaboration revenue of $5.3 million and $4.7 million for the nine

months ended September 30, 2026 and 2025, respectively, related to the Kaken Collaboration Agreement. At inception of the contract, we allocated the transaction price to the License Obligation and Development Services Obligation by allocating the transaction price based on the relative standalone selling price of each obligation. The license revenue was recognized upon the transfer of the license to Kaken in March 2025. We expect to recognize revenue under the Development Services Obligation and Manufacturing Services Obligation through the term of the Kaken Collaboration Agreement as the services are performed. See Note 8 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Research and Development Expenses

The following tables summarize our external and internal research and development expenses for the three and nine months ended September 30, 2026 and 2025 (dollars in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
External costs:				
CROs, CMOs and clinical trials	$ 33,474	$ 56,457	$ (22,983)	(41)%
Professional consulting services	8,237	8,227	10	0 %
Other research and development costs	5,740	1,617	4,123	255 %
Internal costs:				
Personnel-related costs	27,220	24,854	2,366	10 %
Facilities and overhead costs	6,121	6,681	(560)	(8)%
Total research and development expense	$ 80,792	$ 97,836	$ (17,044)	(17)%

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
External costs:				
CROs, CMOs and clinical trials	$ 114,839	$ 187,618	$ (72,779)	(39)%
Professional consulting services	23,662	22,047	1,615	7 %
Other research and development costs	11,496	6,908	4,588	66 %
Internal costs:				
Personnel-related costs	80,497	69,334	11,163	16 %
Facilities and overhead costs	17,175	17,306	(131)	(1)%
Total research and development expense	$ 247,669	$ 303,213	$ (55,544)	(18)%

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

Research and development expenses decreased by $17.0 million, to $80.8 million for the three months ended September 30, 2026, from $97.8 million for the three months ended September 30, 2025.

CRO, CMO and clinical trials expenses decreased by $23.0 million, to $33.5 million for the three months ended September 30, 2026, from $56.5 million for the three months ended September 30, 2025. The decrease was primarily due to lower clinical trial and CRO expenses reflecting the progression of our envu clinical program following the completion of the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials in patients with PsO and a decrease in other program costs, partially offset by an increase in clinical trial and CRO expenses for the Phase 3 ONWARD3 LTE clinical trial and an increase in CRO expenses for the Phase 2b SLE clinical trial.

Other research and development costs increased by $4.1 million, to $5.7 million for the three months ended September 30, 2026, from $1.6 million for the three months ended September 30, 2025, primarily due to increased preclinical research activities supporting our development programs and research pipeline.

Personnel-related costs increased by $2.4 million, to $27.2 million for the three months ended September 30, 2026, from $24.9 million for the three months ended September 30, 2025, primarily due to an increase in research and development headcount, and included an increase of $2.7 million in stock-based compensation expense driven by additional equity awards granted, partially offset by severance costs related to the ACELYRIN Merger incurred in the prior year.

Facilities and overhead costs decreased by $0.6 million, to $6.1 million for the three months ended September 30, 2026, from $6.7 million for the three months ended September 30, 2025, primarily due to a decrease in information technology costs and facilities expenses allocated to research and development activities.

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

Research and development expenses decreased by $55.5 million, to $247.7 million for the nine months ended September 30, 2026, from $303.2 million for the nine months ended September 30, 2025.

CRO, CMO and clinical trials expenses decreased by $72.8 million, to $114.8 million for the nine months ended September 30, 2026, from $187.6 million for the nine months ended September 30, 2025. The decrease was primarily due to lower clinical trial, CRO and CMO expenses reflecting the completion of the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials in patients with PsO and a decrease in other program costs, partially offset by an increase in clinical trial and CRO expenses for the Phase 3 ONWARD3 LTE clinical trial.

Professional consulting services expenses increased by $1.6 million, to $23.7 million for the nine months ended September 30, 2026, from $22.0 million for the nine months ended September 30, 2025. The increase was primarily due to higher professional services costs incurred to support the envu clinical program related to reporting of topline results for the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials and data for our Phase 3 ONWARD3 LTE in patients with PsO and our plan to submit an NDA by the end of 2026, as well as our Phase 2b SLE clinical trial.

Other research and development costs increased by $4.6 million, to $11.5 million for the nine months ended September 30, 2026, from $6.9 million for the nine months ended September 30, 2025, primarily due to increased preclinical research activities supporting our development programs and research pipeline.

Personnel-related costs increased by $11.2 million, to $80.5 million for the nine months ended September 30, 2026, from $69.3 million for the nine months ended September 30, 2025, primarily due to an increase in research and development headcount, and included an increase of $7.8 million in stock-based compensation expense driven by additional equity awards granted, as well as employer contributions to our 401(k) plan reflecting a matching program effective January 1, 2026, partially offset by severance costs related to the ACELYRIN Merger incurred in the prior year.

External Costs by Program

The following table summarizes our external costs by program for the three and nine months ended September 30, 2026 and 2025 (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Envu	$ 42,013	$ 48,866	$ 129,542	$ 179,986
A-005	292	2,499	1,823	8,849
Other programs and research and development activities	5,146	14,936	18,632	27,738
Total external research and development expense	$ 47,451	$ 66,301	$ 149,997	$ 216,573

During the three and nine months ended September 30, 2026, our external research and development expenses were primarily related to the clinical development of the envu program and, to a lesser extent, the A-005 and other development programs, and our research pipeline.

General and Administrative Expenses

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

General and administrative expenses increased by $0.7 million, to $20.2 million for the three months ended September 30, 2026, from $19.5 million for the three months ended September 30, 2025.

Personnel-related expenses increased by $0.3 million, to $11.3 million for the three months ended September 30, 2026, from $11.0 million for the three months ended September 30, 2025, primarily due to an increase of $1.8 million in stock-based compensation expense driven by additional equity awards granted, partially offset by severance costs related to the ACELYRIN Merger incurred in the prior year.

Professional consulting services expenses increased by $0.4 million, to $8.4 million for the three months ended September 30, 2026, from $8.0 million for the three months ended September 30, 2025, primarily due to an increase in costs to support our launch preparation efforts, partially offset by legal expenses and other costs incurred in the prior year.

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

General and administrative expenses decreased by $14.1 million, to $62.2 million for the nine months ended September 30, 2026, from $76.3 million for the nine months ended September 30, 2025.

Personnel-related expenses decreased by $7.0 million, to $32.9 million for the nine months ended September 30, 2026, from $39.9 million for the nine months ended September 30, 2025, primarily due to severance costs related to the ACELYRIN Merger incurred in the prior year including a decrease of $2.3 million in stock-based compensation expense driven by severance-related equity awards, partially offset by an increase in compensation costs consistent with an increase in headcount.

Professional consulting services expenses decreased by $7.8 million, to $27.5 million for the nine months ended September 30, 2026, from $35.3 million for the nine months ended September 30, 2025, primarily due to ACELYRIN Merger transaction costs incurred in the prior year and a decrease in accounting and consulting costs, partially offset by legal expenses and other costs, and an increase in costs to support our launch preparation efforts.

Intangible Assets Impairment Loss

Intangible assets impairment loss was $41.8 million for the nine months ended September 30, 2026 and related to the acquired IPR&D intangible asset recognized in the ACELYRIN Merger. In May 2026, we completed our strategic review of the lonigutamab program and decided to pursue strategic alternatives for the program, which resulted in an impairment

assessment of the related acquired IPR&D intangible asset and the recognition of an impairment loss of $41.8 million. No impairment loss was recognized for the three months ended September 30, 2026. See Note 6 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Other Income (Expense), Net

Total other income (expense), net decreased by $0.3 million to $4.2 million for the three months ended September 30, 2026, from $4.5 million for the three months ended September 30, 2025. Total other income (expense), net decreased by $184.0 million, to $14.4 million for the nine months ended September 30, 2026, from $198.4 million for the nine months ended September 30, 2025.

Gain on bargain purchase was $187.9 million for the nine months ended September 30, 2025, and represented the excess of the fair value of net assets acquired in the ACELYRIN Merger over the purchase consideration on the Closing Date. The gain was recognized during the three months ended June 30, 2025.

Interest income increased by $4.0 million to $14.6 million for the nine months ended September 30, 2026, from $10.6 million for the nine months ended September 30, 2025, primarily due to higher average balances of cash equivalents and marketable securities.

Income Tax Benefit

Income tax benefit was zero and $1.8 million for the three and nine months ended September 30, 2026, respectively, as compared to zero and $8.6 million for the three and nine months ended September 30, 2025. The income tax benefit for the nine months ended September 30, 2026 was recognized in June 2026 in connection with the impairment of our acquired IPR&D intangible asset and was primarily related to a reduction in the associated deferred tax liability, partially offset by an increase in the valuation allowance. The income tax benefit for the nine months ended September 30, 2025 was recognized during the three months ended June 30, 2025 in connection with the ACELYRIN Merger and was related to the realization of deferred tax assets and the release of the related valuation allowance.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity and Going Concern

Since our inception, we have primarily funded our operations through the issuance of common stock, including in connection with the ACELYRIN Merger and our IPO and a concurrent private placement transaction, the issuance of redeemable convertible preferred stock and convertible promissory notes in private placements, and, most recently, the public offering of common stock which closed on January 9, 2026, as well as cash payments received under the Kaken Collaboration Agreement.

We expect to continue to incur substantial losses for the foreseeable future, and our ability to achieve and sustain profitability will depend upon successful development, approval and commercialization of any product candidates we may develop, and on achievement of sufficient revenue to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital.

Based on our current operating plan, our existing cash, cash equivalents and marketable securities of $431.3 million as of September 30, 2026, will not be sufficient to meet our operating and capital requirements for at least 12 months from the date of issuance of the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q and there is substantial doubt about our ability to continue as a going concern. Our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q do not include any adjustment that may result from the outcome of this uncertainty.

We will need to raise significant additional capital to fund ongoing research and development activities, support potential commercialization including market and launch preparation activities and maintain future operations. We plan to monitor operating expenses and may reduce our operating expenses and may raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. For example, we may scale back or discontinue clinical development activities and reallocate our working capital to extend our ability to meet our operating and capital requirements. Our ability to access capital when needed is not assured and, if capital is not available to us when, and in the amounts, needed, on terms that are favorable, we could be required to delay, scale back, or abandon some or all of our planned development programs and other operations, which could materially harm our business, financial condition and results of operations.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all, and our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the effects of ongoing military conflicts, inflationary pressures, potential future bank failures, or otherwise. In this regard, the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the United States, Israel and Iran have created extreme volatility in the global credit and financial markets and have had and may continue to have further global economic consequences, including continued disruptions of the global supply chain and energy markets, which could continue to drive inflationary pressures and increase global recession risk. Accordingly, we could experience an inability to access additional capital or our liquidity could otherwise be impacted. 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and any future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and any future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- the cost of manufacturing clinical and commercial supplies as well as scale up of our current and any future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to establish new, strategic collaborations, licensing or other arrangements;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the timing of when we pay our operating expenses;
- the effect of competing technological and market developments;
- 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 amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (248,153)	$ (297,616)
Net cash (used in) provided by investing activities	(151,050)	192,864
Net cash provided by financing activities	367,229	749
Net decrease in cash, cash equivalents and restricted cash	$ (31,974)	$ (104,003)

Operating Activities

Net cash used in operating activities was $248.2 million and $297.6 million for the nine months ended September 30, 2026 and 2025, respectively.

Net cash used in operating activities for the nine months ended September 30, 2026 included net loss of $330.2 million, partially offset by non-cash items totaling $81.9 million and changes in operating assets and liabilities of $0.1 million. Non-cash items included $41.8 million related to intangible assets impairment loss, $40.9 million related to stock-based compensation expense, $2.6 million related to depreciation and amortization, $1.6 million related to non-cash lease expense and $0.4 million related to impairment of long-lived assets, partially offset by $5.5 million related to net accretion of discounts on marketable securities. The changes in operating assets and liabilities included an increase of $5.5 million in research and development accrued expenses, a decrease of $3.9 million in other assets, non-current and an increase of $2.8 million in deferred revenue, partially offset by a decrease of $4.0 million in other accrued expenses and current liabilities, a decrease of $3.4 million in operating lease liabilities, a decrease of $1.8 million in deferred tax liability, a decrease of $1.2 million in accounts payable, an increase of $1.1 million in other prepaid expenses and other assets, and an increase of $0.5 million in research and development prepaid expenses.

Net cash used in operating activities for the nine months ended September 30, 2025 was due to our net loss for the period of $150.4 million and non-cash items totaling $152.0 million partially offset by changes in operating assets and liabilities of $5.0 million. Non-cash items included $187.9 million related to gain on bargain purchase in connection with the ACELYRIN Merger and net accretion of discounts on marketable securities of $3.9 million, partially offset by $35.4 million related to stock-based compensation expense, $2.6 million related to depreciation and amortization, $1.2 million related to non-cash lease expense and $0.5 million related to impairment of long-lived assets. The changes in operating assets and liabilities included a decrease of $13.3 million in other prepaid expenses and other assets, a decrease of $9.4 million in research and development prepaid expenses, an increase of $4.9 million in research and development accrued expenses, an increase of $2.6 million in other accrued expenses and current liabilities, an increase of $1.9 million in deferred revenue, and an increase of $0.2 million in other liabilities, non-current, partially offset by a decrease of $11.6 million in accounts payable, a decrease of $8.6 million in deferred income tax liability, an increase of $5.1 million in other assets, non-current, and a decrease of $2.3 million in operating lease liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 of $151.1 million was related to purchases of marketable securities of $503.9 million and purchases of property and equipment of $0.9 million, partially offset by proceeds from maturities of marketable securities of $353.7 million.

Net cash provided by investing activities for the nine months ended September 30, 2025 of $192.9 million was related to proceeds from maturities of marketable securities of $305.4 million and cash, cash equivalents and restricted cash acquired in connection with the ACELYRIN Merger of $49.7 million, partially offset by purchases of marketable securities of $161.6 million and purchases of property and equipment of $0.7 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 of $367.2 million was related to proceeds from public offering of common stock, net of underwriting discounts, commissions and offering costs of $323.8

million, proceeds of common stock upon exercise of stock options of $41.9 million and proceeds from the issuance of common stock under the 2024 ESPP of $1.6 million.

Net cash provided by financing activities for the nine months ended September 30, 2025 of $0.7 million was primarily related to proceeds from the issuance of common stock under the 2024 ESPP.

Contractual Obligations and Commitments

Leases

We have operating lease arrangements for office and laboratory space in South San Francisco, California and office space in Southern California. As of September 30, 2026, we had total undiscounted lease payment obligations under non-cancelable leases of $48.7 million, including $2.1 million payable through December 31, 2026. See Note 10 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

FronThera Contingent Consideration

On March 5, 2021, we entered into the FronThera Acquisition, which was accounted for as an asset acquisition. Under the stock purchase agreement, we are obligated to pay contingent consideration of up to an aggregate of $120.0 million based on the achievement of specified clinical and approval milestones, consisting of up to $70.0 million for clinical milestones, and of up to $50.0 million for approval milestones, including receipt of first commercialization approval in the United States or certain other jurisdictions, all related to technology acquired under the agreement. As of September 30, 2026, we had achieved and paid two clinical milestones totaling $60.0 million. No additional milestones were achieved or were probable of being achieved as of September 30, 2026.

License and Commercialization Agreement with Pierre Fabre

Upon the closing of the ACELYRIN Merger, we became the successor to ACELYRIN's rights and obligations under the Pierre Fabre Agreement. We received certain exclusive worldwide licenses with the right to sublicense certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a "PF Licensed Product"). The Pierre Fabre Agreement prohibits us from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

We are obligated to (i) make payments of up to $100.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event we enter into a sublicense with a third party, we must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense relates to.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if we or any of our affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. We may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

No milestones were achieved or were probable of being achieved as of September 30, 2026.

Purchase Commitments

We enter into contracts in the normal course of business with suppliers, CROs, CMOs and clinical trial sites. Upon the closing of the ACELYRIN Merger, we became the successor to contracts with non-cancellable obligations under ACELYRIN contracts. The total value of non-cancellable obligations under contracts was $0.3 million as of September 30, 2026. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of our engagements.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported expenses during the reporting period. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in the Annual Report on Form 10-K filed with the SEC on March 19, 2026. If actual results or events differ materially from the estimates and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no material changes to our critical accounting policies from those described in the Annual Report on Form 10-K for the year ended December 31, 2025.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) 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 revenues 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 the market value of our common stock and non-voting common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (b) 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 Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock and non-voting common stock held by non-affiliates was less than $250.0 million as of June 30, 2025. We may continue to be a smaller reporting company if either (i) the market value of our common stock 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 the market value of our common stock 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. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and marketable securities. However, due to the nature of these cash equivalents and marketable securities, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States, and our expenses are generally denominated in U.S. dollars. However, we utilize certain CRO and CMO vendors outside of the United States for our clinical trials and product development and manufacturing. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2026, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of September 30, 2026, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and the benefits of controls and procedures must be considered relative to their costs.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-FMO-MAA), naming ACELYRIN and then-current and former executive officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial evaluating izokibep in hidradenitis suppurativa. The original complaint was filed following ACELYRIN's announcement of the week 16 results from the Part B portion of such Phase 2b trial. The amended complaint seeks damages and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the Court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the Court, with leave to amend, in January 2026. On February 5, 2026, the plaintiffs filed a second amended complaint, which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the Court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. We could be forced to expend significant resources in the defense against this and any other related lawsuits and we may not prevail.

From time to time, we may become involved in additional legal proceedings arising in the ordinary course of business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Quarterly Report on Form 10-Q. We cannot assure you that any of the events discussed below will not occur. These events could adversely impact our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Summary of Risks

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

- There is substantial doubt about our ability to continue as a going concern and we will require substantial additional financing to achieve our goals; failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

- We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients, the availability of competitive products and significant competition for recruiting participants in clinical trials.

- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

- Our clinical trials may reveal serious adverse events ("SAEs") and significant adverse events ("AEs") and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of envu, A-005 or any future product candidates.

- We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies and/or candidates under development in our current indications.

- Our business is highly dependent on the success of our most advanced product candidate, envu, and we cannot guarantee that envu will successfully complete development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

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

- We are dependent on the services of our management team and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

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

- We cannot ensure that patent rights relating to inventions described and claimed in our or any current or future licensors' and licensees' pending patent applications will issue or that patents based on our or any current or future licensors' and licensees' patent applications will not be challenged and rendered invalid and/or unenforceable.

- We have and may continue to form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.

- Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory

obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our (including the third parties with whom we work) 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 consequences for our business, results of operations and financial condition

- We may have conflicts with any current or future licensors, licensees, collaborators or strategic partners that could delay or prevent the development or commercialization of our product candidates.

Risks Related to Our Financial Position and Need for Capital

There is substantial doubt about our ability to continue as a going concern and we will require substantial additional financing to achieve our goals; failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $431.3 million. We incurred a net loss of $94.9 million and $330.2 million for the three and nine months ended September 30, 2026, respectively. We expect to continue to incur substantial losses for the foreseeable future. Based on our current operating plan, our existing cash, cash equivalents and marketable securities will not be sufficient to meet our operating and capital requirements for at least 12 months from the date of issuance of the unaudited condensed consolidated financial statements included in Part I Item 1 of this Quarterly Report on Form 10-Q and there is substantial doubt about our ability to continue as a going concern.

We are evaluating additional strategies to obtain funding for future operations. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. For example, in March 2026, we entered into a Sales Agreement with Cantor, pursuant to which we may offer and sell, from time to time through Cantor, at our option, shares of our common stock having an aggregate offering price of up to $300.0 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to sales under the Sales Agreement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. We could also be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Based on our current operating plan, we will need to raise additional financing to continue our products' development and support potential commercialization, including market and launch preparation activities, for the foreseeable future, and until we become profitable, if ever. Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, the perception of our ability to continue to operate as a going concern may make it more difficult to obtain financing for the continuation of our operations. If we are unable to obtain funding when and as needed on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining additional financing. Therefore, we cannot be certain that our plans to raise additional capital will be successful in alleviating the substantial doubt regarding our ability to continue as a going concern. If we do not obtain additional financing and are required to terminate our operations, our stockholders will lose all or a part of their investment.

We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. We have no product candidates approved for commercial sale, have not generated any revenue from product sales and have incurred substantial losses since our inception. Biopharmaceutical product development is a highly speculative undertaking. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our most advanced candidate is envu, an oral, small molecule allosteric inhibitor of TYK2. We completed the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials of envu in patients with PsO and reported positive topline results in the first quarter of 2026. We plan to submit an NDA for envu in PsO to the FDA by the end of 2026. We are also evaluating envu in ongoing OLE trials in patients with PsO. In September 2026, we reported topline results from Part A of our Phase 2b clinical trial evaluating envu in patients with SLE. In addition, we are advancing A-005, an investigational CNS penetrant allosteric inhibitor of TYK2 that has a potential application in Parkinson's disease and other neuroinflammatory and neurodegenerative diseases, and are planning to initiate a Phase 2 biomarker trial of A-005 in Parkinson's disease in 2027. Our ability to achieve profitability in the future is dependent upon obtaining regulatory approval for and successfully commercializing our most advanced candidate, envu, either alone or with third parties. However, our operations may not be profitable even if envu is successfully developed, approved and thereafter commercialized.

We have and will continue to incur significant development and other expenses related to our research and clinical development programs and ongoing operations. Net loss was $94.9 million and $110.8 million for the three months ended September 30, 2026 and 2025, respectively, and $330.2 million and $150.4 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $1,232.0 million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct preclinical studies and clinical trials for envu, A-005 and potential future programs;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;

- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and seeking regulatory approval for our product candidates due to public health concerns, macroeconomic conditions or geopolitical conflicts; and
- incur costs associated with operating as a public company.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also 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 or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the institutional review boards ("IRBs") or ethics committees of the institutions in which such trials are being conducted, the FDA or other comparable foreign regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension, clinical hold or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs or clinical trial sites to perform in accordance with good clinical practices ("GCP") requirements, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. For example, our Phase 2b clinical trial of envu in patients with SLE failed to achieve its primary and secondary endpoints as announced in September 2026 and we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our research or development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed

on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients, the availability of competitive products and significant competition for recruiting participants in clinical trials.

Participant enrollment, a significant factor in the timing of clinical trials, is affected by many conditions, including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain participant consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us. Our clinical trials will compete with other clinical trials for product candidates that are in the same areas as our product candidates, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or to use currently marketed therapies. Additionally, participants, including participants in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling participants in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We have in the past experienced and expect to continue to experience participant withdrawals or discontinuations from our trials. For example, as long-term treatment with envu continues to be evaluated in our STRIDE OLE, ONWARD3 LTE study and LUMUS OLE, we expect to see discontinuation rates rise over time. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

Risks Related to Product Candidate Development and Commercialization

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

Our product candidates are either in clinical or preclinical development, and their risk of failure is high. It is impossible to predict when or if our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans for their intended uses. Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug ("IND") application or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before allowing us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs.

Once initiated, clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. For example, lonigutamab's potential to improve on the safety and side-effect profile of the sole currently-approved therapy in the United States for the treatment of TED is unproven. In particular, if lonigutamab is shown to have similar adverse events or side effects as the existing therapy, or other safety or tolerability concerns, such as hearing impairment, then an opportunity to disrupt the current standard of care in TED will be limited or precluded altogether. In this regard, ACELYRIN observed certain adverse events in its Phase 2 clinical trial of lonigutamab including, without limitation, headache, tinnitus and injection site reactions. Following completion of our strategic review of the lonigutamab program, we decided to pursue strategic alternatives for lonigutamab. There can be no assurance that any such strategic alternative will be successfully identified or consummated on favorable terms, if at all, and the foregoing observed adverse events, among other factors, could limit our ability to realize value from the program. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials, and we have experienced and may experience setbacks in our programs in the future. For example, our Phase 2b clinical trial evaluating envu in patients with SLE failed to achieve its primary and secondary endpoints as announced in September 2026, and we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of such product candidates.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or any future collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, may disagree with the design or implementation of our clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, IRBs or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not allow us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- we may be unable to identify, recruit or train suitable clinical investigators;

- clinical trial sites may deviate from trial protocol or drop out of a trial;
- we may be unable to complete our clinical trials due to trial participant withdrawals and discontinuations due to AEs or otherwise;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds to initiate or complete a clinical trial or to pay the substantial user fees required by the FDA upon the submission of an NDA or comparable marketing authorization application in another jurisdiction;
- the quality or quantity of supply relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates;
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- our CROs or clinical trial sites may fail to perform in accordance with GCP requirements or other applicable regulations, rules or guidelines;
- we may be unable to manufacture our product candidates from our CMOs in accordance with cGMP regulations or other applicable requirements in sufficient quantities for use in our clinical trials;
- SAEs may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- we may select clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- we may be required to transfer our manufacturing processes to larger-scale facilities operated by a different CMO, or may experience delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties may be unwilling or unable to satisfy their contractual obligations to us in a timely manner, or at all.

In addition, we have historically leveraged our extensive analyses of immune-relevant genome-wide association study ("GWAS") results from both the public domain and the UK Biobank biomedical resource to identify the right therapeutic target on which to focus our preclinical and clinical development efforts.

If our access to GWAS results from the public domain or the UK Biobank biomedical resource were to be restricted, including as a result of any potential future legislative policies or regulations that may seek to restrict the sharing of genetic data, our ability to efficiently identify additional therapeutic targets may be limited.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional

government regulations may be enacted. In the EU, the EU Clinical Trials Regulation ("CTR") became applicable on January 31, 2022, repealing and replacing the Clinical Trials Directive. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state, leading to a single decision for each EU member state. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU member states in which the trial is to be conducted, and a separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

Moreover, following a public consultation that began in 2022, the government of the United Kingdom ("UK") has enacted new legislation to overhaul the clinical trials regulatory framework. In April 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, remove unnecessary administrative burdens on trial sponsors, and protect the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials into closer alignment with the CTR. The amendment became applicable on April 28, 2026 following a one-year transition period. While these changes introduce efficiencies and align with some principles of the EU's CTR, divergence between the UK and EU regulatory systems remains. Any significant divergence could affect the cost and complexity of conducting clinical trials in the UK and may impact the acceptability of UK-based trial data for seeking marketing authorizations in the EU, and vice versa.

Our clinical trials may reveal SAEs and AEs and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of envu, A-005 or any future product candidates.

Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive labeling or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

We have observed SAEs and AEs in our trials of envu, and as more patients become exposed to envu over longer periods of time, we expect to see additional SAEs and AEs emerge. Further, long term treatment with envu continues to be evaluated in OLE trials, and we anticipate additional AEs and SAEs will continue to accumulate. Certain conditions occur more frequently in patients with psoriasis compared to the general population. Examples include obesity, cardiovascular disease, psoriatic arthritis and depression. Immune modulating treatments including envu may result in increasing susceptibility to various infections, including serious or life-threatening infections, and there is a theoretical risk with immune-modulating agents that dampening immune responses could increase the risk of malignancies.

Other TYK2 inhibitors, such as deucravacitinib (marketed as Sotyktu), which is approved for the treatment of adults with PsO, have shown AEs such as hypersensitivity reactions, infections, tuberculosis, malignancy and rhabdomyolysis. The label for deucravacitinib includes a warning concerning the potential for JAK-related AEs, such as cardiovascular and thrombotic events. We have observed, and expect that additional AEs and SAEs consistent with known side effects of TYK2 inhibition may emerge, in our ongoing and future clinical trials of envu.

The most common AEs observed in our Phase 3 trials that were considered related to envu treatment by the principal investigator include headaches, upper respiratory tract infections, nasopharyngitis and acne. We continue to evaluate the safety profile of envu in our ongoing Phase 2 OLE and Phase 3 program.

If AEs, SAEs or other side effects are observed in any of our ongoing or future clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. If such effects are more severe or less reversible than we expect, or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of envu, A-005 or any future product candidates, which could result in the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

If envu fails to demonstrate an acceptable benefit/risk profile, versus current approved therapies or others in clinical

development, then our opportunity to disrupt the current standard of care may be limited. AEs and SAEs that emerge during clinical investigation of or treatment with envu, A-005, or any future product candidates have in the past been and may in the future be deemed to be related to our product candidates. This may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain envu, A-005 or any future product candidates and could result in warnings and precautions in our product labeling or a restrictive risk evaluation and mitigation strategy ("REMS") or comparable foreign strategies. This may also result in an inability to obtain approval of envu, A-005 or any future product candidates. We, the FDA or other comparable foreign regulatory authorities, or an IRB or ethics committee, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects, like those mentioned above, may limit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or comparable foreign strategies or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw, suspend or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; and
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies.

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

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

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

data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose data from interim analyses from our clinical trials. Interim analyses from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data, topline data, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory authorities, 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 and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

We have conducted, are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted, are currently conducting, and may in the future conduct, clinical trials outside the United States, including (without limitation) in the EU, the UK, Japan, Latin America and Asia-Pacific countries. We expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA 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 being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive regulatory approval for our current or future product candidates in the United States, we may never receive regulatory approval to market outside of the United States.

We plan to seek regulatory approval for our current and future product candidates outside of the United States and are currently conducting certain clinical trials internationally, including in the EU and Japan. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve

additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The regulatory approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health payors and insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with envu, A-005 or any of our future product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ “therapeutic category” price referencing and seek to lower the reimbursement levels for all treatments in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to successfully commercialize our product candidates, if approved.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance

that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, biopharmaceutical products and services are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In some countries, separate pricing and reimbursement approvals may be required before a product can be commercially launched. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries allow companies to establish their own prices for medical products but monitor and control company profits or control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, medicinal products may be subject to Health Technology Assessments ("HTA") at the EU and national levels. HTA is a multidisciplinary process that assesses information regarding the medical, patient and social aspects, as well as economic and ethical issues, related to the use of a health technology. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. At the EU level, on January 12, 2025, Regulation No. 2021/2282 on Health Technology Assessment ("HTA Regulation") entered into application through a phased implementation. The HTA Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. The HTA Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It enables EU Member States to use common tools, methodologies, and procedures and requires them to take into account EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved.

Further, the containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years and biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Such increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. In the event Most-Favored-Nation pricing for pharmaceutical products is implemented and applicable to any of our product candidates that may receive regulatory approval, our revenue opportunities may be adversely affected, as our U.S. pricing would have to be reduced to the lowest price paid for the applicable product outside of the United States. In such event, we may choose to forgo the ex-U.S. market to preserve more favorable U.S. pricing.

We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies and/or candidates under development in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do, and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data, emerge.

Our current product candidates, initially under development for treatment of patients with immune-mediated diseases, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing envu for the treatment of PsO and SLE. Other emerging and established life sciences companies have been focused on similar therapeutics and indications. If approved, envu would compete with several currently approved or late-stage oral clinical therapeutics in each such indication as well as other drugs used to treat such patients.

We are also developing A-005, which has potential applications in Parkinson's disease and other neuroinflammatory and neurodegenerative diseases.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provide a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel in establishing clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Risks Related to Our Business and Operations

Our business is highly dependent on the success of our most advanced product candidate, envu, and we cannot guarantee that envu will successfully complete development, receive regulatory approval or be successfully commercialized. If we are

unable to develop, receive regulatory approval for and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, envu, which is still in clinical development, and expect that we will continue to invest heavily in envu, as well as our second product candidate, A-005, and any future product candidates we may develop. Additionally, in May 2026, we completed our strategic review of the lonigutamab program, ACELYRIN's lead product candidate. While we decided to pursue strategic alternatives for the lonigutamab program, there can be no assurance that any such strategic alternative will be successfully identified or consummated on favorable terms, if at all. Our business and our ability to generate revenue from product sales, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We currently generate no revenue from product sales, and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons, including the negative impacts of geopolitical instability, public health crises, labor shortages, inflation or other macroeconomic factors impacting our third-party CROs, CMOs, clinical trial sites, investigators or us. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve primary or secondary endpoints in clinical trials. For example, our Phase 2b clinical trial evaluating envu in patients with SLE failed to achieve its primary and secondary endpoints as announced in September 2026, and we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success. Additionally, we may in the future advance envu, A-005 or future product candidates into clinical trials and terminate such trials prior to their completion.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

We have not previously submitted an NDA or similar marketing application to the FDA or comparable foreign regulatory authorities for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Although we plan to submit an NDA for envu for PsO by the end of 2026, we will need to meet with the FDA and they may raise concerns or requirements that delay submission beyond our anticipated timeline. After submission of the NDA, the FDA may issue us a Refusal to File letter if the NDA is not sufficiently complete to permit substantive review. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of any NDA we may submit, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical study design. Such changes could delay approval or necessitate withdrawal of any such NDA submission. Similar risks may exist in foreign jurisdictions.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- price our products competitively such that third-party and government reimbursement permits broad product adoption;

- demonstrate the superiority of our products compared to the standard of care, as well as to other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval of an NDA or Biologics License Application from the FDA. Similar approvals are required in order to market product candidates in foreign countries. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate based on adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that our product candidates will receive regulatory approval. Even though our topline data readout of our Phase 3 pivotal trials of envu in PsO was positive, they may not be sufficient for approval of envu in that disease, and our Phase 3 LTE trial in PsO remains ongoing. Although we have discussed and intend to further discuss our Phase 3 clinical trial design and overall development plan with the FDA to align on its sufficiency to support an NDA submission, the feedback is typically non-binding and dependent on the strength of the ultimate clinical data and the FDA's perspective on the benefit-risk profile of the treatment in the intended population. For example, the Committee for Medicinal Products for Human Use in the EU provided comments on the length of our two pivotal 24-week

Phase 3 trials, and we plan to address their feedback with our comparator trials. These modifications could delay our development timelines for EU regulatory approval and require substantially more resources. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. In addition, we have a Phase 2b trial of envu in SLE ongoing. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our development timelines or permit competitors to obtain approvals that may alter our strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

In addition, if the FDA or comparable foreign regulatory authorities grant approval for our product candidates, then, as a condition for approval, the FDA or comparable foreign regulatory authorities may require us to perform costly post-marketing testing, including Phase 4 clinical trials or surveillance to monitor the effects of the marketed product.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- the FDA or comparable foreign regulatory authorities will review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve our CMOs' manufacturing process or facilities with respect to our product candidates; 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.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS or comparable foreign strategies, which may be required because the FDA or comparable foreign regulatory authority believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, FDA and foreign regulatory authorities may change their policies and new regulations may be enacted. In April 2023, the European Commission proposed a comprehensive overhaul of EU pharmaceutical legislation (the "Pharma Package"). On December 11, 2025, the European Parliament and the Council reached a provisional political agreement on the Pharma Package, which comprises a new directive and regulation intended to replace significant portions of the existing EU pharmaceutical framework. The reform encompasses a broad range of measures, including, among other things, changes to regulatory data and market protection periods, intellectual property exemptions intended to facilitate earlier generic and biosimilar market entry, marketing authorization procedures, and measures relating to the availability and supply of medicinal products. Under the agreed framework, medicinal products would generally benefit from eight years of regulatory data protection and one year of market protection, with opportunities to obtain additional market protection if specified conditions are satisfied. The Council formally adopted its first-reading position on September 28, 2026. The legislation remains subject to formal adoption by the European Parliament, following which it will be published in the Official Journal of the European Union. The new framework is expected to be subject to transitional arrangements, with general application not anticipated before 2028. Any reduction in regulatory protection available for our product candidates, together with measures facilitating earlier generic or biosimilar market entry, as applicable, could increase competition and adversely affect the commercial prospects of any product candidates we are able to commercialize in the EU.

Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities caused by funding shortages, government shutdowns or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory, and policy changes, the FDA's or comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of other government agencies 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 or comparable foreign authorities may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies or regulatory authorities, 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 authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, such as the U.S. government shutdown in the fourth quarter of 2025, or if global health concerns prevent the FDA or other comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales

will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's approved labeling, including potential limitations on the use of the product or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to such product candidates or to which we agree as part of a mandatory REMS or risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration or compliance with administration instructions of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid or comparable foreign programs;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and

- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

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

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our most advanced product candidate, envu, currently in development for the treatment of PsO and SLE, and our second product candidate A-005, currently in development for the treatment of neuroinflammatory and neurodegenerative diseases. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing 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 product candidates. For example, our Phase 2b clinical trial of envu in patients with SLE failed to achieve its primary and secondary endpoints as announced in September 2026, and we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success. 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 will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of September 30, 2026, we had 251 full-time and 2 part-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources.

In addition, we have limited experience in manufacturing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we expect to continue to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with future collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our management team and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon the members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these

agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to continue to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater San Francisco Bay Area. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and other parties. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, respect our confidentiality and intellectual property rights, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval for our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Similar requirements apply in foreign countries. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or comparable foreign regulatory authorities, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid or comparable foreign programs, integrity oversight and reporting obligations, or reputational harm.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and growth prospects.

We conduct business globally and our operations, including third-party suppliers, span numerous countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The ongoing trade tensions between the United States and other jurisdictions have resulted in multiple rounds of tariffs and potential tariffs affecting pharmaceuticals and pharmaceutical ingredients, including finished drug products, manufacturing equipment and related supplies. In April 2025, the U.S. government imposed a 10% baseline global tariff and subsequently imposed higher "reciprocal" tariffs on numerous territories, including EU member states and South Korea. In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act did not authorize the President to impose

tariffs, invalidating tariffs imposed pursuant to that authority. Following the Supreme Court's decision the Trump Administration imposed a temporary global tariff under Section 122 of the Trade Act of 1974, which has since expired. Other tariffs imposed under separate authorities, including those under Section 232 of the Trade Expansion Act of 1962 on certain pharmaceutical ingredients, remain in effect, and the Trump Administration has continued to pursue additional tariff measures under other trade authorities. The U.S. trade and tariff landscape continues to evolve, and the scope, timing and duration of existing and potential tariffs remain uncertain.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, most of our suppliers are located outside of the United States, and our principal suppliers of critical raw materials are located in India and in Taiwan. We also rely on precursor compounds, other materials, and manufacturing services sourced from multiple countries, including the EU and South Korea, to advance our research and development and manufacturing efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients ("APIs"), raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt additional non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the U.S. and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and have imposed and may continue to impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and growth prospects. In addition, tariff and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report on Form 10-Q.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the EU, the UK and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for our product candidates. To

obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval for our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to these risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA or other regulatory authority investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension, variation or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could 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 commercial general liability, general liability, cyber liability, workers' compensation, clinical trials and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

We have engaged in, and may in the future engage in, strategic transactions, which could impact our liquidity, increase our expenses, dilute our stockholders and present significant distractions to our management.

We have in the past and may continue to enter into strategic transactions, including acquisitions of companies, asset purchases and in-licensing of intellectual property with the potential to acquire and advance new assets or product candidates where we believe we are well qualified to optimize the development of promising therapies. For example, we were founded in January 2021, and subsequently acquired envu via a stock purchase of FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC. Additionally, we consummated the ACELYRIN Merger in May 2025 and acquired lonigutamab. Additional potential transactions that we may consider in the future include a variety of business arrangements, including strategic partnerships, in-licensing or out-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any such 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. Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. For example, as a result of the ACELYRIN Merger, we now operate our historical core business along with the acquired ACELYRIN business as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. We have also incurred substantial expenses in connection with and as a result of completing the ACELYRIN Merger. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, including in connection with the ACELYRIN Merger, could have a material adverse effect on our business and adversely affect our results of operations and financial condition. Additionally, we may not realize the anticipated benefits of the ACELYRIN Merger or any other such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame. 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 adversely affect our business, financial condition, results of operations and prospects.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had U.S. federal net operating loss carryforwards of $281.2 million and U.S. states net operating loss carryforwards of $5.9 million. Under the Internal Revenue Code, our U.S. federal net operating losses arising in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such U.S. federal net operating losses in a taxable year is limited to 80% of taxable income in such year.

In addition, under Sections 382 and 383 of the Internal Revenue 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 certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As of December 31, 2025, we completed a Section 382 analysis which indicated that we have experienced an ownership change and resulted in the expiration of U.S. federal net credits before utilization and, as such, we recognized a reduction of deferred tax assets. There may be additional ownership changes in the future, some of which may be outside of our control. If we undergo an ownership change, and our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes (if any) is limited, such limitation could harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. The One Big Beautiful Bill Act (the

"OBBBA") enacted in July 2025, the Inflation Reduction Act ("IRA") enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 made many significant changes to the U.S. tax laws. For example, the Tax Cuts and Jobs Act required taxpayers to capitalize and amortize U.S.-based and non-U.S.-based research and experimental ("R&E") expenditures over five and fifteen years, respectively. The OBBBA restores the deductibility of domestic R&E expenditures in the year incurred for tax years beginning after December 31, 2024, but retains the capitalization and amortization requirement for foreign R&E expenditures. In addition, the IRA includes provisions that impact the U.S. federal income taxation of certain corporations, including a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that is imposed on the corporation repurchasing such stock. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation, possibly with retroactive effect. Additionally, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

If our information technology systems, or those used by our CROs, CMOs, clinical sites or other third parties with whom we work or our data are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, regulatory investigations or actions, litigation, fines, penalties and liability, and other adverse consequences to our business, results of operations and financial condition.

In the ordinary course of our business, we, and the third parties with whom we work, process personal information and other sensitive data, including intellectual property, trade secrets, proprietary or confidential business information, preclinical and clinical trial data, personal information related to relevant stakeholders, third-party data, and other sensitive data (collectively, sensitive information) and as a result, we and the third parties with whom we work face a variety of evolving threats which could cause security incidents affecting or interruptions to our information technology systems and sensitive information.

Our information technology systems and those of our CROs, CMOs, clinical sites and other third parties with whom we work are vulnerable to attack, damage and interruption from a variety of evolving threats, including but not limited to computer viruses, misconfigurations, software bugs, worms, or other vulnerabilities and malicious codes, malware (including ransomware and as a result of advanced persistent threat intrusions), application security attacks, social engineering (including through phishing attacks and deep fakes, which may be increasingly more difficult to identify as fake), supply chain attacks and vulnerabilities through our third-party service providers, denial or degradation-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, fraud, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, adware, telecommunications and electrical failures, terrorism, war, earthquakes, fires, floods, and other similar threats. Such threats are prevalent, are occurring more often, 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. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive information), loss of income, significant extra expenses to restore data or systems, reputational loss, the diversion of funds and other consequences. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Some actors also now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war

and other major conflicts, we, and the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems, operations and supply chain. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data 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.

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

Furthermore, future or past business transactions (such as the ACELYRIN Merger or other 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. Additionally, 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 acquired entities into our information technology environment and security program.

We have in the past and may in the future expend significant resources and modify our business activities to try to protect against security incidents. While we take steps designed to anticipate, detect and remediate threats and vulnerabilities, because the threats and techniques used to exploit such vulnerabilities and gain unauthorized access to, to sabotage or otherwise compromise systems change frequently, are often sophisticated in nature, and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement and maintain adequate preventative measures. Therefore, such vulnerabilities have and could be exploited but may not be detected until after a security incident has occurred. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities and we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can be no assurance that our information security policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and sensitive information.

Our reliance on third-party service providers could introduce additional cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems and to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data hosting, encryption and authentication technology, personnel email, human resource management, training and other functions. We also rely on third-party service providers to assist with our clinical trials or otherwise to operate our business, including to manage and store sensitive patient data from our clinical trials. 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. Our third-party service providers have and may in the future experience a security incident or other interruption. 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. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support our operations.

We and certain of our service providers have been and are from time to time subject to cyberattacks and security incidents. Any of the previously identified or similar threats have or could cause a security incident or other interruption that resulted or results in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure, or other processing of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to conduct clinical trials. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's or vendors' use of generative Artificial Intelligence ("AI") technologies.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

If the information technology systems of our CROs, CMOs, clinical sites and other third parties become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Our contracts may not contain liability limitations and, even where they do, there can be no assurance that such limitations are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. Further, our cyber liability insurance coverage may not be sufficient to cover the financial, legal, business reputational or other losses that may result from an interruption or breach.

Security incidents have and could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of sensitive information, we could incur liability and the further development of any product candidates could be delayed.

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

Security incidents (or perceived security incidents), may result in material adverse consequences such as legal claims or proceedings, liability including litigation exposure, penalties and fines under relevant legal obligations, enforcement actions and investigations by regulatory authorities, additional reporting requirements or oversight, restrictions on processing sensitive information (including personal information), indemnification obligations, monetary fund diversions, diversion of management attention, other financial loss, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates, any of which may adversely affect our business, results of operations or financial condition.

Our operations are predominantly concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire, earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party service providers, such as our CMOs and CROs located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical trial sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans that we and third parties upon whom we rely have or may have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our cash and cash equivalents may be exposed to failure of our banking institutions.

While we seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in a number of large financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the "FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the "Federal Reserve"), and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, the FDIC and the Federal Reserve have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, the FDIC and the Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we expect to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us.

These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current

and/or projected business operations and financial condition and results of operations.

In addition, one or more of our critical vendors, third party manufacturers, or other business partners could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. In addition, side effects generally associated with TYK2 or JAK inhibitors may negatively impact public perception of us or envu and A-005. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

Any additional future impairment of the acquired IPR&D intangible asset related to the ACELYRIN Merger may negatively affect our results of operations and financial position.

In May 2026, following completion of our strategic review of the lonigutamab program, we decided to pursue strategic alternatives for the program. This decision represented a triggering event requiring us to perform an interim impairment assessment of the acquired IPR&D intangible asset related to the ACELYRIN Merger. Based on the results of the impairment assessment, we recognized an impairment loss of $41.8 million in June 2026. The impairment loss reduced the carrying amount of the acquired IPR&D intangible asset to its estimated fair value of $9.1 million as of June 30, 2026. No additional impairment loss was recognized for the three months ended September 30, 2026. Indefinite-lived intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should any additional future impairment of indefinite-lived intangible assets occur.

Risks Related to Intellectual Property

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

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. 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 product candidates and novel discoveries that are important to our business. Our pending and future patent applications may not result in patents being issued. We cannot assure you that 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, invalidated by third parties, or effectively prevent others from commercializing competitive products or product candidates.

Obtaining and enforcing patents is expensive 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 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 have in the past and will continue to enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, 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 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. However, we cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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 U.S. 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 or in-licensed patent applications may not result in issued patents that protect our product candidates effectively to prevent others from commercializing our 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 issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our 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 pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO, or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations, interferences, inter partes review ("IPR") 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 product candidates, or limit the duration of the patent protection of our 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 patent rights are invalid or unenforceable in a litigation. An adverse result in any legal proceeding could put one or more of our owned or in-licensed 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 product candidates might expire before or shortly after such candidates are commercialized. 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.

We cannot ensure that patent rights relating to inventions described and claimed in our or any current or future licensors' and licensees' pending patent applications will issue or that patents based on our or any current or future licensors' and licensees' patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors, licensees or collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have several pending United States and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; or
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our or any current or future licensors' pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our or any current or future licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or any current or future licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or any current or future licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our or any current or future licensors' portfolio may not adequately exclude third parties from

practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid 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, and filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive. 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 or any current or future licensors' inventions in all countries outside the United States, even in jurisdictions where we or any current or future licensors do pursue patent protection, or from selling or importing products made using our or any current or future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or any current or future licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or any current or future licensors 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 or any current or future licensors' 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 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 or any current or future licensors' patents or marketing of competing products in violation of our proprietary rights.

Certain 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 current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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 in the future.

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 product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or any patents or patent applications that we currently in-license or may in-license in the future;

- we or any current or future licensors or collaborators might not have been the first to make the inventions covered by the pending patent application that we own or may in-license in the future;

- we or any current or future 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 or otherwise violating our owned intellectual property rights or any patent applications that we may license in the future;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies' requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents, if any arise in the future, that we either own or that we may license in the future may be revoked, modified, or held invalid or unenforceable, 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 non-exclusive 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;
- we cannot predict the scope of protection of any patent issuing based on our or any current or future licensors' patent applications, including whether the patent applications that we own, or, in the future, in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and

- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Should any of these or similar events occur, they could significantly harm 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 United States 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 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 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, that may be infringed by the manufacture, use or sale of our product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our 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 current technology, including our research programs, 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.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter

infringement or unauthorized use, we or any current or future licensors 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 or any current or future licensors' 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 patents or any current or future licensors' 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 or any current or future licensors 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 or any current or future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any current or future licensors' 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 or any current or future licensors' patents could limit our ability to assert our or any current or future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive 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, 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 claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may become involved in third-party claims of intellectual property infringement, which may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. 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 their intellectual property rights. Numerous United States 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. 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 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 preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. 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.

Patent applications can take many years to issue. 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. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates, if approved, may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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. 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. 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 not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates, if approved. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, if approved, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting 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.

We may become subject to claims challenging the inventorship or ownership of our or any current or future licensors' patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or any current or future licensors' 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.

Any current or 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 these licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could 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. 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 have and may continue to form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.

The current, and any future, collaborations that we enter into may not be successful and we may not enter into such collaborations at all. The success of our collaboration arrangements will depend heavily on the efforts and activities of any future collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;

- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and

- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property for the development of lonigutamab. For example, we depend on licenses from Pierre Fabre for certain intellectual property relating to the development and commercialization of lonigutamab in specific territories.

Pierre Fabre may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors, including Pierre Fabre, fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize lonigutamab could be adversely affected. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize lonigutamab or our other product candidates in the future.

In spite of our efforts, licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. In addition, our exploration and any potential consummation of strategic alternatives for the lonigutamab program may require us to seek amendments to, or waivers under, our existing license agreement with Pierre Fabre, and there can be no assurance that such amendments or waivers would be agreed to on commercially acceptable terms or at all. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. 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 (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- our financial or other obligations under the license agreement;

- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those obligations;

- the inventorship or 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.

In addition, our license agreements are, and any future license agreements 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 increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or may license in the future prevent or impair our ability to maintain our current or future licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

We have entered into, and may in the future enter into, license agreements that subject us to certain rights retained by third parties.

We have entered into the Kaken Collaboration Agreement with Kaken, pursuant to which we have granted Kaken an exclusive license to develop, manufacture and commercialize envu for dermatology indications in Japan. Under the Kaken Collaboration Agreement, Kaken has options to expand the license into rheumatological and gastrointestinal indications in Japan, and Kaken is responsible for the clinical development, regulatory approvals and commercialization of envu in Japan in dermatology and other indications for which Kaken has exercised its option. We retain global rights to envu outside of those granted to Kaken. In addition, any future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and it is our policy to avoid engaging, university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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.

As is the case with other biopharmaceutical companies, 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 (the "Leahy-

Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of patent applications filed after March 2013 and the enforcement or defense of our future issued patents or claiming priority to patent applications filed after March 2013. 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 PGR, IPR, 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 or any current or future licensors' 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 or any current or future licensors' patent applications and the enforcement or defense of our or any current or future licensors' 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. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or any current or future licensors 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 or any current or future licensors 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 or any current or future licensors' 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. However, 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 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 United States 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 or any current or future licensors' ability to obtain new patents and patents that we or any current or future licensors might obtain in the future. 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.

In 2012, the European Union Patent Package ("EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits

of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

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 patents and patent applications. We rely on our outside patent counsel 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. 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.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest 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 competitive products, including generics or biosimilars. 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.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA regulatory approval of our product candidates, one or more of our issued United States patents or issued United States patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under SPC. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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 seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. 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 to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, 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. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Monitoring and detecting unauthorized disclosure or other compromise of trade secrets is difficult, and we do not know whether the steps we have taken to prevent such compromise are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our business, including confidential aspects of sample preparation, methods of manufacturing, proprietary assays, computational-biological algorithms, data analytics and machine learning related to genetics, genomics, proteomics, biomarkers and samples, and related processes and software, are based on unpatented trade secrets, including those of our collaborators. For example, our collaborator, Foresite Labs, utilizes extensive trade secret algorithms, machine learning and AI analysis techniques, and we rely on their maintenance of these trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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 may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our 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 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.

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 unregistered trademarks, trade names or future registered trademarks 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 name 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.

Risks Related to Government Regulation

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements.

The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. Comparable foreign regulatory authorities may have similar authority. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will have limited control over compliance with applicable rules and regulations by such manufacturers.

In addition, any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. For example, the FDA and comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses, as the FDA and comparable foreign regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, the FDA and such comparable foreign regulatory authorities do restrict promotional communications from companies or their sales force with respect to off-label uses of products. Specifically, any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA, and our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. Similar restrictions apply in other countries. In the EU, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") which may require approval by the competent national authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. If we are found to have promoted such off-label uses, we may become subject to significant liability. In addition, if we do not conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we promote our products, if approved, in a manner inconsistent with FDA-approved labeling, or the labeling approved by another comparable foreign regulatory authority, or otherwise not in compliance with FDA regulations or comparable foreign rules, we may be subject to enforcement action. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure by us, our contract manufacturers or service providers, or collaborators to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- operating restrictions;
- holds on clinical trials;
- warning or untitled letters;
- refusal by the FDA or comparable foreign regulatory authorities to approve, or delays in the approval of, pending applications or supplements to approved applications;

- suspension, variation or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

The FDA's and comparable foreign regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, the U.S. Supreme Court's June 2024 decision to overturn 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, and/or changes. As a result of the U.S. Supreme Court's decision, the FDA and other agencies may be less inclined to engage in formal regulation and may rely to a greater degree on informal guidance, which may not always be susceptible to immediate challenge. We cannot predict the likelihood, nature or extent of government regulation or guidance that may arise from future court decisions, legislation, or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of

foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse, referred to as TrumpRx, for patients to purchase certain products from manufacturers on a cash pay basis; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among other things, impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We expect that these and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This assessment of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the original country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states. On January 12, 2025, the HTA Regulation entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. The HTA Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It enables EU Member States to use common tools, methodologies, and procedures and requires them to take into account EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU member states for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Our operations and relationships with healthcare providers, healthcare organizations and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our arrangements with healthcare providers, healthcare organizations and third-party payors will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates, if approved. Restrictions under applicable federal, state and foreign anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the Health Insurance Portability and Accountability Act ("HIPAA"), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by the clinicians described above and their immediate family members;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

In the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU member states. The provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national transparency and reporting rules may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g. annual) basis.

If we or our future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or comparable foreign regulatory authorities, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid or comparable foreign programs, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a study that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our (including the third parties with whom we work) 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 consequences for our business, results of operations and financial condition.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive information). Our data processing activities presently and may in the future 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.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Additionally, the California Consumer Privacy Act ("CCPA") applies to personal information of California consumers, business representatives, and employees, and among other things requires regulated businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. In addition, although the CCPA includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal data and our compliance costs depending on how it is interpreted. Similar laws are being considered or have been enacted in several other states, as well as at the federal and local levels. While certain U.S. state privacy laws, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

There are also various laws, regulations and industry standards in other jurisdictions outside the United States relating to data privacy and security, with which we presently or in the future may need to comply. For example, the EU's General Data Protection Regulation ("EU GDPR") and the UK's equivalent ("UK GDPR"), collectively, GDPR, impose strict requirements for processing personal information (referred to as "personal data" under the GDPR). Notably, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or, in each case, 4% of the annual global revenue of the noncompliant undertaking, whichever is greater. The GDPR also provides for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Additionally, EU member states may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to process such special categories of personal data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

Certain of our employees, other personnel and/or vendors use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Any errors, flaws or other unintended issues in or associated with AI inputs, outputs or technologies could result in adverse impacts on our business. Governments have passed and are likely to pass additional laws regulating generative AI. Our, or our vendors', use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we, or our vendors, are unable to use generative AI, it could make our business

less efficient in some cases, and result in increased costs or competitive disadvantages.

In addition, we may be unable to transfer personal information from Europe and other jurisdictions to the United States 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 information to other countries. In particular, the European Economic Area (the "EEA") and the UK have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it generally believes are inadequate. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, the EU-US Data Privacy Framework, and the UK extension thereto ("Data Privacy Framework") (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Data Privacy 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 information to the United States.

Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. If there is no lawful manner for us to transfer personal information from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions 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 information necessary to operate our business. Additionally, companies that transfer personal information out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States are also increasingly scrutinizing certain personal information transfers and have enacted certain restrictions on cross-border data transfers. For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours that process key-coded clinical trial data and biospecimens.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security obligations, whether by us, one of our CROs, CMOs or another third party with whom we work, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: regulatory investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation (including class claims); consent orders regarding our data privacy and security practices; requirements that we provide notices, bans on processing personal information (including clinical trial data), orders to destroy or not use personal information, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals in the event of an information security

incident impacting personal information; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the GDPR has increased our responsibility and liability in relation to sensitive information that we process, including in clinical trials, that is subject to the GDPR, and we may be required to put in place additional mechanisms to comply with the GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. For instance, in Europe, the second Network and Information Security Directive ("NIS2") aims to improve the resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2, as applicable to us, may lead to administrative fines of a maximum of €10 million or up to 2% of the total worldwide turnover of the preceding financial year. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy, data protection and security in the United States, the EEA, the UK and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations. Any actual or perceived failure by us or third parties with whom we work to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we (or third parties with whom we work) may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure, or other compromise of data that we store or handle as part of operating our business. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials and the development of product candidates); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

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

We also publicly post privacy policies, marketing materials, whitepapers, and other statements concerning data privacy, security, and our collection, use, disclosure and other processing of the personal information provided to us or that we collect. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Regulators in the United States and elsewhere are increasingly scrutinizing these statements, and our publication of our privacy policies and other statements we publish that provide promises and assurances about data privacy and security can subject us to potential claims if they are found to be deceptive, unfair, misleading, or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release, transfer or other compromise of personal information or other sensitive information, may result in enforcement actions and prosecutions, private litigation (including class action claims), significant fines, penalties (including bans on processing personal information or orders to destroy or not use personal information) and censure, claims for damages by affected

individuals, regulatory inquiries and investigations or adverse publicity and could cause reputational harm, any of which could adversely affect our business, financial condition, results of operations and prospects. The successful assertion of one or more large data privacy or security claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Risks Related to Our Reliance on Third Parties

We may have conflicts with any current or future licensors, licensees, collaborators or strategic partners that could delay or prevent the development or commercialization of our product candidates.

We are currently party to the Kaken Collaboration Agreement and the license and collaboration agreement with Pierre Fabre, and we may enter into strategic transactions in the future, and we may have conflicts with our current or future licensors, licensees, collaborators or strategic partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into future additional collaborations; unwillingness by such collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiation of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have if we had conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We have no experience as a company in submitting and supporting the applications necessary to gain regulatory approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with good laboratory practices, where applicable, and clinical trials are conducted in accordance with GCPs and applicable rules. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including through inspections that may be conducted once we submit an NDA to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, 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. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, and foreign equivalents.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our future collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

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

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third parties for the manufacture

of APIs, bulk drug substances, raw materials, samples, components and other materials for our product candidates for clinical testing, as well as for the manufacture of any product candidates that we commercialize, if approved. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, if any biotechnology companies or CMOs become subject to trade restrictions, sanctions, or other regulatory requirements by the U.S. government, such actions could restrict or even prohibit our ability to work with such entities. Such disruption could have adverse effects on the development of our product candidates and our business operations. Also, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

We obtain our preclinical and clinical supplies from our manufacturers on a purchase order basis, and currently do not have long-term supply arrangements in place. The manufacturing process for our product candidates is subject to the FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, and comparable foreign regulatory authorities. If the FDA or any comparable foreign regulatory authority determines that our third-party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny any NDA or marketing application we submit until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is able to demonstrate a compliance status acceptable to the FDA or foreign regulatory authority. Moreover, we are dependent on our CMOs for manufacturing in compliance with cGMPs and other regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. We will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. If we are required to change manufacturers, the delays and costs associated with the verification of a new manufacturer, whether due to failure to comply with regulatory requirements, or quality, timing and supply issues, or other reason, could negatively affect our ability to develop product candidates in a timely manner or within budget.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, improving product formulations, increasing manufacturing success rate or other reasons. For example, we are implementing certain manufacturing process changes for envu to increase scalability with respect to our Phase 3 clinical trials. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies or clinical bridging studies, and we may be required to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we enter into future long-term manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and comparable foreign regulatory authorities,

including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of future collaborators;
- sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures of product candidates or drugs, operating restrictions and criminal prosecutions;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants once approved, would be jeopardized.

We depend on limited source suppliers for certain raw materials used in our product candidates. If we are unable to source these supplies on a timely basis or establish redundancy in our manufacturing process or longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

Certain of the raw materials necessary to produce envu and A-005 are in limited supply, and we generally rely on one CMO for each manufacturing stage. While we intend to identify and qualify additional suppliers and redundant manufacturers to provide the API, drug product and critical raw material prior to regulatory approval and/or a comparable marketing application outside the United States, there can be no assurance that we will be successful in doing so. Furthermore, any of the limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Establishing redundancy in CMOs and additional or replacement suppliers for these supplies, and obtaining regulatory authorizations that may result from adding or replacing CMOs and suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

In addition, we do not currently have long-term supply contracts with our CMOs, and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all.

While we intend to enter into long-term master supply agreements with certain of our CMOs prior to any potential marketing approval, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines, or at all, or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to the contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

The operations of our suppliers, most of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, most of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- fluctuations in currency exchange rates over time, which may substantially increase our costs of doing business abroad where we have payment obligations in local currency;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries particularly China;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters, including, for example, disruptions experienced during the COVID-19 pandemic;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We may be exposed to significant currency exchange risk.

We operate a number of our clinical trials outside of the United States and incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to currency exchange risk as our results of operations and cash flows are subject to fluctuations in currency exchange rates. Fluctuations in currency exchange rates have had, and will continue to have, an impact on our results as expressed in United States dollars. We currently do not have a formal hedging program with respect to foreign currencies. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Risks Related to Ownership of Our Common Stock

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

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol "ALMS". However, we cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market or your ability to resell your shares of our common stock at or above the price you paid for them. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net losses and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our most advanced product candidate envu, A-005 and other development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under any current or future license and future collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including any future acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as

an indication of our future performance.

Our stock price is likely to continue to be volatile, which could result in substantial losses for our investors.

The market price of our common stock is likely to continue to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- announcements regarding our ability and anticipated timelines to submit applications for regulatory approvals of envu in PsO;
- regulatory approval or non-approval of envu in PsO, specific label indications for or restrictions, warnings or limitations in its use or delays in the regulatory review process;
- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or any future collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to any future strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- our ability to achieve the perceived benefits of our strategic transactions, including the ACELYRIN Merger, as rapidly or to the extent anticipated by financial analysts or investors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;

- pandemics, natural disasters, or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled "Risk Factors."

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock could cause our stock price to fall.

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

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations, including conducting our planned clinical trials, manufacturing and commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

Based on the beneficial ownership of our capital stock as of September 30, 2026, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 33% of our outstanding voting stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. In addition, as a result of this concentration of ownership, there is a limited number of shares of our common stock that are not held by officers, directors and controlling stockholders (which is referred to as our public float), thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which you may be able to sell shares of common stock.

We are an "emerging growth company" and a "smaller reporting company," and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to the other public companies that are not "emerging growth companies," including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and

stockholder approval of any golden parachute payments not approved previously. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations in this report. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. These provisions allow an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of such extended transition period. We cannot predict whether investors will find our common stock less attractive as a result of its reliance on these exemptions. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile than the current trading market and price of our common stock.

Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, we will incur additional compliance costs, which may impact our financial condition.

We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have a total annual gross revenue of $1.235 billion; (ii) the last day of our fiscal year following the fifth anniversary of the completion of our IPO; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the end of the fiscal year in which the market value of common stock held by non-affiliates exceeds $700 million as of the prior June 30. Even after we no longer qualify as an emerging growth company, we may continue to 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 addition, as a smaller reporting company with less than $100 million in annual revenue, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

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

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

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

- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

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

Our amended and restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

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

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"), including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

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

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your 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. 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 ownership and other limitations provided for in our certificate of incorporation. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

General Risk Factors

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

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (for example, related to the evolving U.S. and ex-U.S. tariff landscape). Further, the United States and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods. For example, in April 2025, the U.S. government imposed a 10% baseline global tariff and subsequently imposed higher "reciprocal" tariffs on numerous territories, including EU member states and South Korea. In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act did not authorize the President to impose tariffs, invalidating tariffs imposed pursuant to that authority. Following the Supreme Court's decision, the Trump Administration imposed a temporary global tariff under Section 122 of the Trade Act of 1974, which has since expired. Other tariffs imposed under separate authorities, including those under Section 232 of the Trade Expansion Act of 1962 on certain pharmaceutical ingredients, remain in effect, and the Trump Administration has continued to pursue additional tariff measures under other trade authorities. The U.S. trade and tariff landscape continues to evolve, and the scope, timing and duration of existing and potential tariffs remain uncertain. Given the volatility and uncertainty regarding the scope and duration of tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations

and financial results remains uncertain. Likewise, our financial condition and results of operations may continue to be affected by global volatility and general market disruption resulting from geopolitical tensions, such as the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the United States, Israel and Iran. In particular, the continued escalation of hostilities in the Middle East, including involving Iran, could further disrupt global energy markets, fuel prices, transportation networks, and supply chains, which may disrupt or otherwise negatively impact our supply chain and increase our costs. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

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

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

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing Section 404(b) of the Sarbanes-Oxley Act, which requires including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we are required to comply with the SEC's rules implementing Sections 302 and 404(a) of the Sarbanes-Oxley Act, which require our management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Furthermore, as an emerging growth company, our independent registered public accounting firm will

not be required to attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404(b). If we identify any material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404(b) in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other comparable foreign regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

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

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

ACELYRIN has been named a defendant in a purported securities class action lawsuit, and we may be the target of other securities litigation in the future. This could result in substantial damages or other expenses and could divert management's time and attention from our business.

In connection with the ACELYRIN Merger, we assumed the liabilities of ACELYRIN, which include a purported federal securities class action lawsuit which was commenced against ACELYRIN in the United States District Court for the Central District of California on November 15, 2023. On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024, naming ACELYRIN and current and former officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act in disclosures regarding the primary endpoint of HiSCR75 at week 16 not meeting statistical significance in ACELYRIN's Phase 2b trial of izokibep in hidradenitis suppurativa. The amended complaint seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the Court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the Court, with leave to amend, in January 2026. On February 5, 2026, the plaintiffs filed a second amended complaint which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the Court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending. This lawsuit is subject to inherent uncertainties, including its outcome. We could be forced to expend significant resources and incur substantial legal fees and costs in the defense of this suit, and we may not prevail. We have not established any

reserve for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. In addition, we may be the target of other securities litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive and time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger, by and among the Registrant, ACELYRIN, Inc. and Arrow Merger Sub, Inc. dated as of February 6, 2025 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 6, 2025).
2.2	Amendment to the Agreement and Plan of Merger, dated as of April 20, 2025 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 21, 2025).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 1, 2024).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 1, 2024).
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 amended, 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 amended, 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 its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Schema Document.
101.CAL*	Inline XBRL Calculation Linkbase Document.
101.DEF*	Inline XBRL Definition Linkbase Document.
101.LAB*	Inline XBRL Label Linkbase Document.
101.PRE*	Inline XBRL Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

* Filed herewith.

\# This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

Date: November 12, 2026

ALUMIS INC.

By: /s/ Martin Babler
Name: Martin Babler
Title: President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ John Schroer
Name: John Schroer
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 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

I, Martin Babler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alumis 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Dated: November 12, 2026

By: /s/ Martin Babler
Name: Martin Babler
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, John Schroer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alumis 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Dated: November 12, 2026

By: /s/ John Schroer
Name: John Schroer
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

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

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

Dated: November 12, 2026

By: /s/ Martin Babler
Name: Martin Babler
Title: Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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

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

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 12, 2026

By: /s/ John Schroer
Name: John Schroer
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.