UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40287

ImageneBio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-1697316**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12526 High Bluff Drive Suite 345 San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 345-6265

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	IMA	The Nasdaq Capital Market

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

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

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

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

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

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

As of October 31, 2026, the registrant had 12,456,281 shares of its voting common stock, $0.001 par value per share, issued and outstanding.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	6
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	6
	Condensed Consolidated Balance Sheets	6
	Condensed Consolidated Statements of Operations and Comprehensive Loss	7
	Condensed Consolidated Statements of Redeemable Convertible Preferred Shares and Stockholders' Equity (Deficit)	8
	Condensed Consolidated Statements of Cash Flows	10
	Notes to Unaudited Condensed Consolidated Financial Statements	11
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	31
PART II.	OTHER INFORMATION	33
Item 1.	Legal Proceedings	33
Item 1A.	Risk Factors	33
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	85
Item 3.	Defaults Upon Senior Securities	85
Item 4.	Mine Safety Disclosures	85
Item 5.	Other Information	85
Item 6.	Exhibits	86
Signatures		87

EXPLANATORY NOTE

On July 25, 2025 (the "Closing Date"), the Delaware corporation formerly known as "Ikena Oncology, Inc." ("Ikena") completed its previously announced merger with Inmagene Biopharmaceuticals, a privately held exempted company with limited liability incorporated and existing under the laws of the Cayman Islands ("Legacy Inmagene"). The transaction was completed in accordance with the terms of the Agreement and Plan of Merger, dated as of December 23, 2024 (the "Merger Agreement"), by and among Ikena, Insight Merger Sub I, an exempted company with limited liability incorporated and existing under the laws of the Cayman Islands and a direct, wholly owned subsidiary of Ikena ("Merger Sub I"), Insight Merger Sub II, an exempted company with limited liability incorporated and existing under the laws of the Cayman Islands and a direct, wholly owned subsidiary of Ikena ("Merger Sub II"), and Legacy Inmagene, providing for the merger of Merger Sub I with and into Legacy Inmagene, with Legacy Inmagene surviving as a wholly owned subsidiary of Ikena (such transaction, the "First Merger"), and the subsequent merger of the surviving entity of the First Merger with and into Merger Sub II, with Merger Sub II surviving as a wholly owned subsidiary of Ikena (the "Second Merger" and, together with the First Merger, the "Merger"). In addition, on July 25, 2025, Ikena changed its name from "Ikena Oncology, Inc." to "ImageneBio, Inc."

Unless otherwise stated or the context otherwise requires, the references in this Quarterly Report to the "Company," "we," "our," or "us" refer to Inmagene Biopharmaceuticals together with its consolidated subsidiaries for periods prior to the Merger and to ImageneBio, Inc. together with its consolidated subsidiaries for periods following the Merger; references to "Ikena" refer to Ikena Oncology, Inc. for periods prior to the Merger; references to "Legacy Inmagene" refer to Inmagene Biopharmaceuticals together with its consolidated subsidiaries for periods prior to the Merger and references to "common stock" refer to the Company's common stock for periods following the Merger and to Legacy Inmagene's ordinary shares for periods prior to the Merger.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- the potential benefits of IMG-007, recently named olevaprubart, including as compared to our competitors' products and product candidates;
- our ability to maintain and protect our intellectual property rights;
- legislative, regulatory, political and economic developments beyond our control and the potential impact on our business;
- our plans and ability to raise significant additional capital to proceed with the development and commercialization of olevaprubart and any future product candidates and to fund our continued operations;
- the initiation, timing and potential of planned or ongoing clinical trials for olevaprubart, including the timing for data readouts;
- our progress, scope or timing of the development of olevaprubart, including our plans to develop olevaprubart for additional immunological and inflammatory indications;
- expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of olevaprubart and anticipated milestones and timing therefor;
- our plans and expectations regarding our current or future collaborations;
- our ability to successfully commercialize olevaprubart, if approved, the rate and degree of market acceptance of olevaprubart and the favorability of pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad;
- our ability to successfully identify and validate new product candidates or additional indications for olevaprubart;
- our planned use of cash, cash equivalents and marketable securities;
- the accuracy of our estimates regarding our cash runway, expenses, future revenue and capital requirements;
- the sufficiency of our internal controls and procedures and our plans and ability to remediate any material weaknesses;
- our expectations and plans regarding legal proceedings against us;
- our ability to recognize the benefits that may be derived from the Merger, including the commercial or market opportunity of olevaprubart;
- developments and projections relating to our competitors, our industry or the market opportunities for olevaprubart or any future product candidates;
- regulatory, political, environmental, economic and public health developments in the United States and foreign countries; and
- other risks and uncertainties, including those under the caption "Risk Factors."

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and undue reliance should not be placed on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in the "Risk Factors" section, which could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or into which we may enter.

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

You should read this Quarterly Report and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Summary of the Material and Other Risks Associated with Our Business

Our business is subject to numerous material and other risks and uncertainties to be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance;
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- We will need to obtain substantial additional funding to complete the development and any commercialization of olevaprubart and any future product candidates, which may cause dilution to our stockholders. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations;
- Our business is entirely dependent on the success of olevaprubart for the treatment of atopic dermatitis ("AD") and alopecia areata ("AA") and for other potential indications;
- Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials;
- If we breach our current or future licenses or other intellectual property-related agreements for olevaprubart or any future product candidates or otherwise experience disruptions to our business relationships with our current or future licensors, we could lose the ability to continue the development and commercialization of our product candidates;
- Our rights to develop and commercialize olevaprubart are subject, in part, to the terms and conditions of licenses granted to us by others;
- We rely on third parties for the manufacture of olevaprubart for development, and expect to continue to do so for the foreseeable future. Our current and anticipated future dependence upon third parties for the manufacture of olevaprubart or any future product candidates increases the risk that we will not have sufficient quantities of olevaprubart or any future product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts and could impact future profit margins;
- We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively;
- The regulatory approval process of the United States Food and Drug Administration ("FDA") and comparable foreign regulatory authorities is lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for olevaprubart or any future product candidates, and any such regulatory approval may be for a more narrow indication than we seek;
- Even if we receive regulatory approval of olevaprubart or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with olevaprubart or any future product candidates;
- If we are unable to obtain and maintain patent protection for olevaprubart or any future product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets;
- Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel;
- The market price of our common stock is expected to be volatile;
- We will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies;
- Substantial future sales of shares of our common stock could adversely affect the market price of such shares;
- If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline; and

- We identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The material and other risks summarized above should be read together with the text of the full risk factors in the "Risk Factors" section and with the other information set forth in this Quarterly Report, including our condensed consolidated financial statements and the related notes, as well as with other documents that we file with the Securities and Exchange Commission (the "SEC"). If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full in the "Risk Factors" section, are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

IMAGENEBIO, 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	$ 84,853	$ 94,532
Marketable securities	41,744	40,817
Prepaid expenses and other current assets	4,000	4,939
Total current assets	130,597	140,288
Operating lease right-of-use assets, net	345	790
Deposits and other non-current assets	6,119	4,878
Promissory note receivable from related party	5,480	7,020
Total assets	$ 142,541	$ 152,976
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 931	$ 1,439
Accrued expenses and other current liabilities	5,832	7,533
Operating lease liabilities, current	1,312	2,262
Total current liabilities	8,075	11,234
Operating lease liabilities, non-current	—	713
Other non-current liabilities	848	870
CVR liability due to related party	5,480	7,020
Total liabilities	14,403	19,837
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Voting Common Stock, $0.001 par value, 142,000,000 shares authorized; 12,456,281 and 10,650,925 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	12	11
Non-Voting Common Stock, $0.001 par value, 8,000,000 shares authorized; no shares issued and outstanding as of September 30, 2026 and 530,714 shares issued and outstanding as of December 31, 2025	—	—
Additional paid-in capital	394,766	363,094
Accumulated other comprehensive income (loss)	(170)	87
Accumulated deficit	(266,470)	(230,053)
Total stockholders' equity	128,138	133,139
Total liabilities and stockholders' equity	$ 142,541	$ 152,976

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ —	$ 800
Operating expenses:				
Research and development	11,270	15,156	23,900	24,849
General and administrative	6,039	11,036	17,272	15,496
Total operating expenses	17,309	26,192	41,172	40,345
Loss from operations	(17,309)	(26,192)	(41,172)	(39,545)
Other income (expense):				
Interest income, net	1,189	1,055	3,566	742
Other income, net	520	284	1,235	288
Total other income, net	1,709	1,339	4,801	1,030
Loss before income taxes	(15,600)	(24,853)	(36,371)	(38,515)
Income tax expense (benefit)	20	(74)	46	(74)
Net loss	(15,620)	(24,779)	(36,417)	(38,441)
Accretion of redeemable convertible preferred shares	—	(846)	—	(7,046)
Net loss attributable to common stockholders	$ (15,620)	$ (25,625)	$ (36,417)	$ (45,487)
Net loss per common share, basic and diluted	$ (0.91)	$ (2.91)	$ (2.45)	$ (9.98)
Weighted-average common shares outstanding, basic and diluted	17,122,691	8,797,126	14,853,552	4,559,574
Comprehensive loss:				
Net loss	$ (15,620)	$ (24,779)	$ (36,417)	$ (38,441)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	(119)	94	(257)	94
Foreign currency translation adjustment	—	(3)	—	(29)
Total comprehensive loss	$ (15,739)	$ (24,688)	$ (36,674)	$ (38,376)

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

IMAGENEBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands, except share data)

	Redeemable Convertible Preferred Shares		Series A Convertible Preferred Shares		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2025	—	$ —	—	$ —	11,181,639	$ 11	$ 363,094	$ 87	$ (230,053)	$ 133,139
Issuance of common stock upon exercise of stock options	—	—	—	—	97,491	—	35	—	—	35
Stock-based compensation expense	—	—	—	—	—	—	876	—	—	876
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(104)	—	(104)
Net loss	—	—	—	—	—	—	—	—	(10,619)	(10,619)
Balances at March 31, 2026	—	—	—	—	11,279,130	11	364,005	(17)	(240,672)	123,327
Issuance of pre-funded warrants for the purchase of common stock	—	—	—	—	—	—	28,048	—	—	28,048
Stock-based compensation expense	—	—	—	—	—	—	911	—	—	911
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	—	—	—	—	(10,178)	(10,178)
Balances at June 30, 2026	—	—	—	—	11,279,130	11	392,964	(51)	(250,850)	142,074
Issuance of common stock upon conversion of pre-funded warrants, net of issuance costs	—	—	—	—	1,038,482	1	(15)	—	—	(14)
Issuance of common stock upon exercise of stock options	—	—	—	—	24,286	—	111	—	—	111
Issuance of common stock in connection with employee stock purchase plan	—	—	—	—	10,013	—	41	—	—	41
Vesting of restricted stock units	—	—	—	—	104,370	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,665	—	—	1,665
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(119)	—	(119)
Net loss	—	—	—	—	—	—	—	—	(15,620)	(15,620)
Balances at September 30, 2026	—	$ —	—	$ —	12,456,281	$ 12	$ 394,766	$ (170)	$ (266,470)	$ 128,138

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

IMAGENEBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands, except share data)

	Redeemable Convertible Preferred Shares		Series A Convertible Preferred Shares		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2024	2,163,434	$ 159,039	994,869	$ 18,967	1,409,884	$ 1	$ 2,158	$ (1,791)	$ (179,900)	$ (160,565)
Issuance of common stock upon exercise of stock options	—	—	—	—	1,763	—	45	—	—	45
Stock-based compensation expense	—	—	—	—	—	—	57	—	—	57
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	3,051	—	—	—	—	(2,244)	—	(807)	(3,051)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	—	—	(6,077)	(6,077)
Balances at March 31, 2025	2,163,434	162,090	994,869	18,967	1,411,647	1	16	(1,800)	(186,784)	(169,600)
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	3,149	—	—	—	—	—	—	(3,149)	(3,149)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	—	—	—	—	(7,585)	(7,585)
Balances at June 30, 2025	2,163,434	165,239	994,869	18,967	1,411,647	1	16	(1,817)	(197,518)	(180,351)
Stock-based compensation expense	—	—	—	—	—	—	15,283	—	—	15,283
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	846	—	—	—	—	—	—	(846)	(846)
Exchange of redeemable convertible preferred shares and convertible preferred shares into common stock upon the closing of the reverse recapitalization	(2,163,434)	(166,085)	(994,869)	(18,967)	3,158,303	3	185,049	—	—	166,085
Issuance costs in connection with reverse recapitalization	—	—	—	—	—	—	(9,431)	—	—	(9,431)
Issuance of common stock to former Ikena stockholders for reverse recapitalization	—	—	—	—	4,071,927	4	83,030	—	—	83,034
Issuance of common stock in PIPE Financing, net of issuance costs of $3.9 million	—	—	—	—	2,508,337	3	71,127	—	—	71,130
Forgiveness of term loan in connection with reverse recapitalization	—	—	—	—	—	—	22,989	—	—	22,989
Issuance of restricted stock units in connection with the reverse recapitalization	—	—	—	—	31,425	—	—	—	—	—
Distribution of Legacy Inmagene CVR to Legacy Inmagene Stockholders	—	—	—	—	—	—	(6,720)	—	—	(6,720)
Non-OX40 Divestiture	—	—	—	—	—	—	1,527	1,820	—	3,347
Unrealized gain on marketable securities	—	—	—	—	—	—	—	94	—	94
Foreign currency translation adjustment	—	—	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	—	—	(24,779)	(24,779)
Balances at September 30, 2025	—	$ —	—	$ —	11,181,639	$ 11	$ 362,870	$ 94	$ (223,143)	$ 139,832

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

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

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (36,417)	$ (38,441)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,452	15,340
Amortization of right-of-use assets	526	466
Accretion of discounts on marketable securities, net	(13)	(33)
Non-cash interest expense	—	489
Depreciation and amortization expense	—	6
Gain on early extinguishment of lease liability	—	(149)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	939	(3,574)
Deposits and other non-current assets	(1,039)	(1,277)
Accounts payable	(654)	(2,179)
Accrued expenses and other current liabilities	1,578	(9,945)
Deferred revenue	—	(650)
Other non-current liabilities	(22)	15
Operating lease liabilities	(1,744)	(694)
Net cash used in operating activities	(33,394)	(40,626)
Cash flows from investing activities:		
Cash divested in Non-OX40 divestiture	—	(5,215)
Purchases of marketable securities	(24,604)	(1,485)
Maturities of marketable securities	23,433	2,250
Net cash used in investing activities	(1,171)	(4,450)
Cash flows from financing activities:		
Proceeds from exercise of stock options	146	45
Proceeds from issuance of common stock in connection with employee stock purchase plan	41	—
Proceeds from issuance of pre-funded warrants to purchase common stock, net of issuance costs	28,034	—
Proceeds from term loan	—	15,000
Payment of issuance costs in connection with reverse recapitalization	(3,279)	(5,338)
Payment of deferred offering costs	(56)	—
Cash acquired in connection with reverse recapitalization	—	54,631
Proceeds from common stock issued in 2025 PIPE Financing, net of issuance costs	—	71,130
Net cash provided by financing activities	24,886	135,468
Effect of exchange rate changes on cash and cash equivalents	—	652
Net change in cash and cash equivalents	(9,679)	91,044
Cash and cash equivalents at beginning of period	94,532	12,118
Cash and cash equivalents at end of period	$ 84,853	$ 103,162
Supplemental disclosure of noncash investing and financing activities:		
Change in right-of-use asset and lease liabilities due to contract modification	$ 81	$ —
Deferred offering costs included in accounts payable	$ 146	$ —
Accretion of redeemable convertible preferred shares	$ —	$ 7,046
Reverse recapitalization issuance costs in accrued expenses	$ —	$ 3,500
Exchange of preferred shares into common stock upon closing of reverse recapitalization	$ —	$ 185,049
Forgiveness of term loan upon closing of reverse recapitalization	$ —	$ 22,989
Issuance of promissory note in connection with divestiture	$ —	$ 6,720
Net assets derecognized in connection with Non-OX40 Divestiture	$ —	$ 5,193

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

IMAGENEBIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization

Nature of Business and Basis of Presentation

ImageneBio, Inc. (collectively, with its consolidated subsidiaries, the "Company") is a clinical-stage biopharmaceutical company developing therapeutics for patients with immunological, autoimmune and inflammatory diseases. The Company's program IMG-007, recently named olevaprubart, is a non-depleting anti-OX40 monoclonal antibody ("mAb") which binds specifically to OX40 receptor on activated T cells to block their binding to OX40 ligand ("OX40L").

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source suppliers, patentability of the Company's product candidate and processes and clinical efficacy and safety of the Company's product candidate, compliance with government regulations and the need to obtain additional financing to fund operations. Olevaprubart or any product candidate the Company may develop will require significant additional research and development efforts, including extensive clinical trials, and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

There can be no assurance that any future research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any product candidate developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if any future product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") for Quarterly Reports on Form 10-Q. The accompanying condensed consolidated financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025, are unaudited. The condensed consolidated balance sheet as of December 31, 2025 was derived from the audited financial statements as of and for the year ended December 31, 2025, but does not include all disclosures required by GAAP. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2025, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2026, the condensed results of its operations for the three and nine months ended September 30, 2026 and 2025, and its cash flows for the nine months ended September 30, 2026 and 2025. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2026 and 2025 are also unaudited. The condensed results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the full year ending December 31, 2026 or any other period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K on file with the SEC. Certain amounts in the three and nine months ended September 30, 2025 have been reclassified to conform to the year ended December 31, 2025 presentation.

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

The Merger

On July 25, 2025 (the "Closing Date"), the Delaware corporation formerly known as "Ikena Oncology, Inc." ("Ikena") completed its previously announced merger with Inmagene Biopharmaceuticals, a privately held exempted company with limited liability incorporated and existing under the laws of the Cayman Islands ("Legacy Inmagene"). The transaction was completed in accordance with the terms of the Agreement and Plan of Merger, dated as of December 23, 2024 (the "Merger Agreement"), by and among Ikena, Insight Merger Sub I, an exempted company with limited liability incorporated and existing under the laws of the Cayman Islands and a direct, wholly owned subsidiary of Ikena ("Merger Sub I"), Insight Merger Sub II, an exempted company with limited liability incorporated and existing under the laws of the Cayman Islands and a direct, wholly owned subsidiary of Ikena ("Merger Sub II"), and Legacy Inmagene, providing for the merger of Merger Sub I with and into Legacy Inmagene, with Legacy Inmagene surviving as a wholly owned subsidiary of Ikena (such transaction, the "First Merger"), and the subsequent merger of the surviving entity of the First Merger with and into Merger Sub II, with Merger Sub II surviving as a wholly owned subsidiary of Ikena (the "Second Merger" and, together with the First Merger, the "Merger"). In addition, on July 25, 2025, Ikena changed its name from "Ikena Oncology, Inc." to "ImageneBio, Inc."

Prior to the effective time of the First Merger (the "First Effective Time"), Ikena effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of its issued common stock ("Ikena Common Stock"). At the First Effective Time, (i) each ordinary share and preferred share of Legacy Inmagene (each such share, a "Legacy Inmagene Share") held as treasury shares immediately prior to the First Effective Time were canceled and ceased to exist, and no consideration was delivered in exchange therefor, (ii) each then-outstanding Legacy Inmagene Share was converted into the right to receive 0.0030510 shares of Ikena Common Stock (such ratio, the "Exchange Ratio") and (iii) each then-outstanding option to purchase Legacy Inmagene Shares was converted into an option to purchase Ikena Common Stock, subject to adjustment as set forth in the Merger Agreement.

All references to common stock, options to purchase common stock, common stock share data, per share data, preferred shares and related information contained in these condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Exchange Ratio for all periods presented, including the change from ordinary shares to common stock, unless otherwise specifically indicated or the context otherwise requires.

The Merger was accounted for as a reverse recapitalization in accordance with GAAP. The Company determined that Legacy Inmagene was the accounting acquirer and Ikena was the accounting acquiree of the Merger in accordance with ASC Topic 805. Management concluded that Legacy Inmagene was the accounting acquirer primarily due to: (i) the Legacy Inmagene stockholders receiving the largest portion of the voting rights in the Company following the First Merger, (ii) Legacy Inmagene's largest shareholder retained the largest interest in the Company, (iii) Legacy Inmagene designated three of the six members to the Company's board of directors on the closing of the Merger, and (iv) certain members of Legacy Inmagene's executive management team became the management of the Company. The condensed consolidated financial statements of the Company reflect the historical operations of Legacy Inmagene for accounting purposes together with the issuance of shares to the former stockholders of Ikena, the legal acquirer, and a recapitalization of the equity of Legacy Inmagene, the accounting acquirer.

Unless otherwise stated or the context otherwise requires, the references in these condensed consolidated financial statements to the "Company," refer to Legacy Inmagene together with its consolidated subsidiaries for periods prior to the Merger and to ImageneBio, Inc. together with its consolidated subsidiaries for periods following the Merger; references to "Ikena" refer to Ikena Oncology, Inc. for periods prior to the Merger; references to "Legacy Inmagene" refer to Inmagene Biopharmaceuticals together with its consolidated subsidiaries for periods prior to the Merger; and references to "common stock" include the Company's common stock for periods following the Merger and to Legacy Inmagene's ordinary shares for periods prior to the Merger.

2025 PIPE Financing

Concurrently with the execution of the Merger Agreement, Ikena entered into subscription agreements with certain accredited investors (the "2025 PIPE Investors"), pursuant to which, immediately following the closing of the Second Merger, the 2025 PIPE Investors subscribed for and purchased, and Ikena issued and sold, an aggregate of 2,508,337 shares of common stock in a private placement at a price of $29.90 per share for aggregate gross proceeds of $75.0 million (the "2025 PIPE Financing").

CVR Agreements

Immediately prior to the First Effective Time, Ikena and the designated rights agent entered into a Contingent Value Rights Agreement (the "Ikena CVR Agreement"), pursuant to which Ikena stockholders of record as of the close of business on July 24, 2025 received one contingent value right (each, an "Ikena CVR") for each outstanding share of Ikena Common Stock held by such stockholder on such date.

Pursuant to the Ikena CVR Agreement, each Ikena CVR holder will be entitled to certain rights to receive (i) 100% of the net proceeds, if any, received by the Company as a result of contingent payments ("Ikena CVR Payments") made to the Company, such as milestone, royalty or earnout payments, received under any disposition agreements related to Ikena's pre-Merger assets, including but not limited to IK-595 (the "Ikena CVR Assets"), including pursuant to any out-license agreements, entered into prior to the Closing Date and (ii) 90% of the net proceeds, if any, received by the Company as a result of Ikena CVR Payments received under any disposition agreements related to the Ikena CVR Assets entered into after the Closing Date and prior to the first anniversary of the Closing Date (the "Disposition Period"). Such proceeds are subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred by the Company or its affiliates, and losses incurred or reasonably expected to be incurred by the Company or its affiliates due to a third-party proceeding in connection with a disposition and certain wind-down costs. The Company has not entered into any transactions subject to the Ikena CVR Agreement. No estimated value has been attributed to the agreement for the periods presented.

Immediately prior to the First Effective Time, Ikena, Legacy Inmagene and the designated rights agent entered into a Contingent Value Rights Agreement (the "Legacy Inmagene CVR Agreement"), pursuant to which Legacy Inmagene's shareholders of record as of immediately prior to the First Effective Time received one contingent value right (each, a "Legacy Inmagene CVR") for each outstanding Legacy Inmagene Share held by such shareholder on such date. Pursuant to the Legacy Inmagene CVR Agreement, each Legacy Inmagene CVR holder will be entitled to certain rights to receive (i) 100% of the net proceeds, if any, received by the Company as a result of contingent payments ("Legacy Inmagene CVR Payments") made to the Company under any disposition agreement related to the programs and projects controlled by Legacy Inmagene any time prior to the Closing Date (other than its anti-OX40 monoclonal antibody asset, olevaprubart) (the "Legacy Inmagene CVR Assets"), which agreement is entered into prior to the Closing Date and (ii) 90% of the net proceeds, if any, received by the Company as a result of Legacy Inmagene CVR Payments received under any disposition agreement related to the Legacy Inmagene CVR Assets entered into during the Disposition Period. Such proceeds are subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred by the Company or its affiliates, and losses incurred or reasonably expected to be incurred by the Company or its affiliates due to a third-party proceeding in connection with a disposition.

Non-OX40 Divestiture

On July 25, 2025, immediately prior to consummation of the Merger, Legacy Inmagene completed the divestiture of the non-IMG-007 business related assets, business and operations (the "Non-OX40 Business") controlled by Legacy Inmagene immediately prior to the Merger (the "Non-OX40 Divestiture"). Specifically, Legacy Inmagene sold and transferred (including via sublicense) all of the Non-OX40 Business to Miragene Inc., a newly formed private company and wholly owned subsidiary of Legacy Inmagene ("Miragene").

As part of the Non-OX40 Divestiture, Miragene Co, a newly formed private company ("BuyCo"), held by the holders of Legacy Inmagene's outstanding shares prior to the Merger, purchased from Legacy Inmagene all of the outstanding share capital of Miragene (holding the Non-OX40 Business) in exchange for a promissory note in the amount of $8.9 million issued by BuyCo to Legacy Inmagene (the "Promissory Note"). BuyCo has been identified as a related party to the Company as there are shareholders in common and the Miragene CEO is a member of the Company's board of directors.

As a result of the Non-OX40 Divestiture, IMG-007, a non-depleting anti-OX40 monoclonal antibody, for the treatment of atopic dermatitis and other potential indications, became the only product candidate of the Company in clinical development.

The Non-OX40 Divestiture resulted in Legacy Inmagene's recognition of $1.5 million within additional paid-in capital, comprised of ($5.2) million in net assets, consisting of $5.2 million in cash transferred to BuyCo for outstanding liabilities associated with the Non-OX40 Business and other insignificant operating assets and liabilities, offset by the initial fair value of the promissory note of $6.7 million during 2025. The Non-OX40 Divestiture represents a transaction between entities with a high degree of common ownership, and therefore, was accounted for like a common control transaction. Accordingly, the assets and liabilities transferred were derecognized at their historical carrying values, and the estimated fair value of the promissory note receivable was recognized, with any difference recorded in equity. No gain or loss was recognized in the consolidated statements of operations and comprehensive loss in connection with this transaction. In addition, the initial estimated fair value of the corresponding Legacy Inmagene CVR liability was recorded as a dividend to the Legacy Inmagene shareholders within equity, with the related payable recorded on the Company's consolidated balance sheets.

Transition Services Agreement

In connection with the Non-OX40 Divestiture, the Company entered into a Transition Services Agreement (the "Transition Services Agreement") with Miragene for the provision by Miragene of certain transitional services related to the ongoing operations of the Company's business with respect to the IMG-007 program (see Note 7).

2026 Private Placement

On April 14, 2026, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors"), including existing investors, pursuant to which the Company issued and sold pre-funded warrants to purchase up to 5,770,335 shares of voting common stock (the "Warrant Shares") at $0.001 per share, in a private placement transaction (the "Private Placement") at a purchase price of $5.199 per Warrant Share to the Investors for gross proceeds of $30.0 million.

Liquidity and Going Concern

The accompanying 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 Company expects to continue to incur losses as it invests in research and development activities to advance its existing and potential future research programs and incurs ongoing costs associated with operating as a public company. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. If the Company obtains regulatory approval for its product candidate or any future product candidates and starts to generate revenue, it expects to incur significant expenses related to developing its internal commercialization capability to support product sales, marketing, and distribution. The Company incurred a net loss of $36.4 million for the nine months ended September 30, 2026 and has an accumulated deficit of $266.5 million as of September 30, 2026. The Company believes its existing cash, cash equivalents and marketable securities of $126.6 million as of September 30, 2026 are sufficient to support operations through at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

The Company will need substantial additional funding to support its operating activities as it advances its product candidate or any future product candidates through development, seeks regulatory approval and prepares for and, if its product candidate or any future product candidates are approved, proceeds to commercialization. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities through a combination of equity offerings, debt financings and license and collaboration agreements. Adequate funding may not be available to the Company on acceptable terms, or at all.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, accrued research and development expenses, stock-based compensation and the fair value of the Promissory Note receivable and related CVR liability. The Company bases its estimates on historical experience, known trends and other factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in facts, circumstances, and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Recently Adopted Accounting Pronouncements

On July 30, 2025, the FASB issued ASU No. 2025-05 *Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides guidance for estimating credit losses under the current expected credit losses (CECL) model for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606. The guidance is effective for periods beginning after December 15, 2025 and is required to be adopted prospectively. The Company adopted ASU No. 2025-05 during the first quarter of 2026 and the adoption did not have a material impact on its condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03 *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)* and provided a clarifying update in January 2025. The amendments increase disclosure requirements primarily through enhanced disclosures about types of expenses (including purchases of inventory, employee compensation, depreciation, and amortization) in commonly presented expense captions. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, and is required to be applied prospectively with the option for retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on the disclosures on its consolidated financial statements.

3. Reverse Recapitalization

The Merger was accounted for as a reverse recapitalization in accordance with GAAP. At the effective time of the Merger, the assets of Ikena primarily consisted of cash and cash equivalents, marketable securities, as well as other nominal assets, including prepaid expenses and other current assets, operating lease right-of-use assets, and other non-current assets. Ikena did not have significant operating activities immediately prior to the closing of the Merger. Under such reverse recapitalization accounting, the assets and liabilities of Ikena were recorded at their fair value in the Company's financial statements at the effective time of the reverse recapitalization, which approximated carrying value. No goodwill or intangible assets were recognized as a result of the reverse recapitalization.

On July 25, 2025, Legacy Inmagene acquired the assets and assumed the liabilities listed below as part of the reverse recapitalization (in thousands):

Cash and cash equivalents	$ 54,631
Marketable securities	40,060
Prepaid expenses and other current assets	2,875
Operating lease right-of-use assets, net	2,428
Other non-current assets	2,666
Accounts payable	(1,808)
Accrued expenses and other current liabilities	(11,367)
Lease liabilities, current and non-current	(5,359)
Other non-current liabilities	(1,092)
Net assets acquired	$ 83,034

Legacy Inmagene incurred transaction costs related to the reverse recapitalization of $9.3 million. This amount was recorded as a reduction to additional paid-in capital during the third quarter of 2025.

4. Fair Value Measurements

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

	Fair Value Measurements at September 30, 2026 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 35,760	$ —	$ —	$ 35,760
Marketable securities:				
Corporate bonds	—	41,744	—	41,744
Promissory note	—	—	5,480	5,480
Total assets	$ 35,760	$ 41,744	$ 5,480	$ 82,984
Liabilities:				
CVR liability	$ —	$ —	$ 5,480	$ 5,480

	Fair Value Measurements at December 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 34,968	$ —	$ —	$ 34,968
Marketable securities:				
Corporate bonds	—	40,817	—	40,817
Promissory note	—	—	7,020	7,020
Total assets	$ 34,968	$ 40,817	$ 7,020	$ 82,805
Liabilities:				
CVR liability	$ —	$ —	$ 7,020	$ 7,020

Money market funds are valued based on quoted market prices, representing a Level 1 measurement within the fair value hierarchy. Corporate debt securities are valued using a market approach based on prices and other relevant information generated by market transactions involving similar instruments. Valuations are obtained from third-party pricing services, which use observable inputs including benchmark yields, reported trades, broker quotes, benchmark securities, and other market-related data. As the valuations are based on observable market inputs for similar instruments, rather than quoted prices for identical instruments in active markets, these securities are classified as Level 2 within the fair value hierarchy.

The Company elected the fair value option and accordingly recorded the Promissory Note receivable at fair value at inception date (July 25, 2025) and each period end, with changes recorded within other income (expense) in the consolidated statements of operations and comprehensive loss. The Company believes the fair value option best reflects the economics of the underlying transaction. The Company's Promissory Note receivable is valued on a recurring basis using a probability weighted expected future payout discounted by applicable market yield of 25.2% and 15.2% as of September 30, 2026 and December 31, 2025, respectively, which are Level 3 inputs.

The Company recorded a corresponding CVR liability in connection with the Promissory Note receivable, with the carrying amount equal to the fair value at inception and each period end, with changes recorded within other income (expense) in the consolidated statements of operations and comprehensive loss.

No cash payments were made for the Promissory Note receivable or the corresponding CVR liability for the periods presented.

The following table presents the changes in fair value of the Promissory Note receivable and the corresponding CVR liability during the nine months ended September 30, 2026 (in thousands):

	Promissory Note Receivable	CVR Liability
Balances at December 31, 2025	$ 7,020	$ 7,020
Change in fair value	(1,290)	(1,290)
Balances at March 31, 2026	5,730	5,730
Change in fair value	(3,170)	(3,170)
Balances at June 30, 2026	2,560	2,560
Change in fair value	2,920	2,920
Balances at September 30, 2026	$ 5,480	$ 5,480

The key inputs for the fair value measurement of the Promissory Note and the CVR liability are the timing of payments and the discount rate. Any payments received under the Promissory Note are payable to Legacy Inmagene CVR holders, and therefore changes in the fair value of the Promissory Note and the corresponding CVR liability offset each other and do not have a material impact on net loss.

During the three and nine months ended September 30, 2026, there were no transfers into or out of Level 3.

5. Marketable Securities

The following tables summarize the Company's available-for-sale securities (in thousands):

	September 30, 2026			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Marketable securities:				
Corporate bonds	$ 41,914	$ —	$ (170)	$ 41,744
Total marketable securities	$ 41,914	$ —	$ (170)	$ 41,744

	December 31, 2025			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Marketable securities:				
Corporate bonds	$ 40,730	$ 88	$ (1)	$ 40,817
Total marketable securities	$ 40,730	$ 88	$ (1)	$ 40,817

The following table provides the maturity of the Company's available-for sale securities as of September 30, 2026 (in thousands):

	September 30, 2026	
	Amortized Cost	Fair Value
Due within one year	$ 28,549	$ 28,469
Due after one year through two years	13,365	13,275
	$ 41,914	$ 41,744

6. Balance Sheet Components

Accrued Expenses and Other Current Liabilities

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

	September 30, 2026	December 31, 2025
Accrued external research and development expenses	$ 2,037	$ 280
Accrued compensation	2,513	2,888
Accrued consulting and professional fees	1,014	875
Accrued financing costs	—	3,326
Accrued other	268	164
Total accrued expenses and other current liabilities	$ 5,832	$ 7,533

Deposits and Other Non-Current Assets

Deposits and other non-current assets primarily include deposits related to clinical trials of $4.8 million and $3.2 million as of September 30, 2026 and December 31, 2025, respectively.

Other Non-Current Liabilities

Other non-current liabilities primarily include liabilities related to uncertain tax positions of $0.8 million as of September 30, 2026 and December 31, 2025.

7. Related Party Transactions

Promissory Note Receivable and CVR Liability

As discussed in Note 1, as part of the Non-OX40 Divestiture in 2025, BuyCo issued a Promissory Note to Legacy Inmagene in the amount of $8.9 million. The Promissory Note accrues interest at an annual rate of 4.61%, with interest payments due monthly in arrears, unless BuyCo elects to capitalize the interest through payment-in-kind (“PIK”) treatment during the term of the Promissory Note. No interest was received pursuant to the Promissory Note Receivable through September 30, 2026. The Promissory Note matures on the earlier of (i) the year 2035 or (ii) the date on which Legacy Inmagene declares the Promissory Note due and payable on or after the occurrence of an event of default. Additionally, in the event that BuyCo receives certain specified milestone or license payments, after the second anniversary of the Promissory Note, 50% of such proceeds must be used to prepay the outstanding balance of the Promissory Note. Any payments received by the Company under the Promissory Note from BuyCo will be distributed to Legacy Inmagene CVR holders as Legacy Inmagene CVR Payments. The Promissory Note receivable is recorded at fair value at each period end (see Note 4).

Transition Services Agreement

In connection with the Non-OX40 Divestiture, the Company entered into the Transition Services Agreement on July 25, 2025 with Miragene for the provision by Miragene of certain transitional services related to the ongoing operations of the Company's business with respect to the IMG-007 program, which may include services related to chemistry, manufacturing and controls, regulatory affairs, clinical trial support and operations, translational science research and support, bioanalysis, pharmacovigilance (collectively, the "Miragene Services").

The initial term of the Transition Services Agreement was six months (the "Initial Term"), with an automatic six-month renewal provision unless written notice was provided. In addition, the Company could extend the Initial Term with respect to any or all of the Miragene Services for up to an additional 12 months upon 60 days' written notice prior to the end of the Initial Term. The Transition Services Agreement could have been terminated after the Initial Term by either party upon 60 days' prior written notice or by Miragene after the completion by the Company of the sale or other disposition of any portion of the Company's business, assets or properties constituting all or a majority of the IMG-007 Business (as defined in the Transition Services Agreement). On October 23, 2025, the Company provided written notice to Miragene of its election to (i) not have the Transition Services Agreement automatically renew and (ii) extend the term for an additional six months following the end of the initial term for a subset of the Miragene Services, including services related to chemistry, manufacturing and controls, translational sciences research and support. On July 25, 2026, the Transition Services Agreement terminated according to its terms.

During the three months ended September 30, 2026, the Company recorded research and development expense of less than $0.1 million in the condensed consolidated statements of operations and comprehensive loss for services under the Transition Services Agreement. During the nine months ended September 30, 2026, the Company recorded research and development expense of $0.3 million and general and administrative expense of $0.1 million in the condensed consolidated statements of operations and comprehensive loss and paid $0.2 million to Miragene for services under the Transition Services Agreement. As of September 30, 2026, all transactions have been fully settled under the Transition Services Agreement. As of December 31, 2025, the Company had prepaid expenses of $0.2 million related to prepayments made under the Transition Services Agreement.

Reimbursement of Research and Development Expenses

Since July 25, 2025, the Company received reimbursement of expenses incurred for agreed upon research and development activities from a related party, where one of the Company's board members is a partner. During the nine months ended September 30, 2026, the Company recorded an offset to research and development expenses in the condensed consolidated statements of operations and comprehensive loss and received a cash payment of less than $0.1 million. During the three and nine months ended September 30, 2025, the Company recorded an offset to research and development expenses in the condensed consolidated statements of operations and comprehensive loss of $0.4 million. As of December 31, 2025, $0.5 million was included as a receivable in prepaid expenses and other current assets, which amount was received in the nine months ended September 30, 2026. As of September 30, 2026, all amounts were fully settled under this arrangement.

2026 Private Placement

On April 14, 2026, certain of the Company's stockholders owning more than 5% of the Company's stock, or entities affiliated with such stockholders, purchased pre-funded warrants to purchase up to 2,211,961 shares of voting common stock at a purchase price of $5.199 for total gross proceeds to the Company of $11.5 million (see Note 8).

8. Stockholders' Equity

2026 Private Placement

On April 14, 2026, the Company issued and sold pre-funded warrants to purchase up to 5,770,335 shares of voting common stock in the Private Placement at a purchase price of $5.199 per Warrant Share to the Investors, including existing investors (see Note 7), for gross proceeds to the Company of $30.0 million. The Company incurred issuance costs of $2.0 million in connection with the issuance of the Warrant Shares.

The pre-funded warrants have an exercise price of $0.001 per Warrant Share, subject to customary adjustments, and are exercisable at any time after original issuance and will not expire until exercised in full. The pre-funded warrants are also exercisable on a net exercise "cashless" basis. The pre-funded warrants may not be exercised if the aggregate number of shares of voting common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation, not to exceed 19.99%.

The pre-funded warrants are recorded net of issuance costs and classified as additional paid-in-capital within stockholders' equity. The pre-funded warrants are classified as equity because they are freestanding financial instruments entered into separately and

apart from any of the Company's other financial instruments or equity transactions, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, are indexed to the Company's common stock and meet the equity classification criteria.

During the three months ended September 30, 2026, investors exercised 1,038,516 pre-funded warrants in exchange for 1,038,482 shares of common stock in a partial cashless exercise. As of September 30, 2026, 4,731,819 pre-funded warrants remain outstanding.

Registration Rights Agreement

In connection with the Private Placement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Investors, pursuant to which the Company agreed to prepare and file, within three business days following August 1, 2026, subject to certain allowable delays, a registration statement with the SEC to register for resale the Warrant Shares, and generally to cause the applicable registration statement to promptly become effective. On August 5, 2026, the Company filed its registration statement on Form S-3 with the SEC for the resale of the Warrant Shares, and it was declared effective on August 11, 2026. The Company will be required to make certain cash payments in the event of registration failures, as described in the Registration Rights Agreement, not to exceed 5% of the aggregate purchase price. As of September 30, 2026, the Company determined that the likelihood of the Company incurring a significant amount of liquidated damages pursuant to the Registration Rights Agreement is not probable.

9. Stock-Based Compensation

The Company adopted the 2025 Equity Incentive Plan (the "2025 Plan") in connection with the Merger, which was approved by Ikena's stockholders at its annual meeting of its stockholders on July 15, 2025 and became effective on the date immediately following the consummation of the Merger. As of the effective time of the 2025 Plan, there were 1,118,167 shares of common stock available for grant under the 2025 Plan. In addition, the number of shares reserved and available for issuance under the 2025 Plan will automatically increase on January 1 of each year for a period of 10 years, commencing on January 1, 2026 and ending on January 1, 2035, in an amount equal to 5% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors. The 2025 Plan is a successor to and continuation of Ikena's 2021 Stock Option and Incentive Plan, as amended (the "2021 Plan"). In addition, the Company assumed, effective as of the closing of the Merger, the Legacy Inmagene 2019 Stock Incentive Plan (the "2019 Plan"). Upon adoption of the 2025 Plan, no further grants will be made under the 2021 Plan or the 2019 Plan. The number of shares reserved for issuance under the 2025 Plan was increased by 559,081 shares effective January 1, 2026 in accordance with the provisions of the 2025 Plan. Additionally, on June 16, 2026, the stockholders of the Company approved the Amended and Restated 2025 Equity Incentive Plan (the "Amended 2025 Plan") to among other things, increase the aggregate number of shares of common stock authorized for issuance under the 2025 Plan by 850,000 shares and to include shares of common stock issuable upon conversion or exercise of convertible preferred stock and pre-funded warrants in the calculation of the annual automatic share reserve increase. As of September 30, 2026, 642,465 shares remain available for issuance under the 2025 Plan.

In July 2025, the Company's board of directors adopted and approved the 2025 Inducement Plan (the "Inducement Plan") to reserve 589,585 shares of common stock to be used exclusively for grants of equity awards to individuals that were not previously employees or directors of the Company (or who are returning to employment following a bona fide period of non-employment), as an inducement material to the individual's entry into employment with the Company, pursuant to Nasdaq Listing Rule 5635(c)(4). The Inducement Plan was adopted and approved without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). On December 18, 2025, the Company's board of directors approved an amendment to the Inducement Plan to increase the maximum aggregate number of shares of common stock issuable thereunder to 1,589,585 shares of common stock. As of September 30, 2026, 538,533 shares remain available for issuance under the Inducement Plan.

The Company adopted the 2025 Employee Stock Purchase Plan (the "2025 ESPP") in connection with the Merger, which was approved by Ikena's stockholders at its annual meeting of its stockholders on July 15, 2025 and became effective on the date immediately following the consummation of the Merger. As of the effective time of the 2025 ESPP, there were 111,816 shares of common stock available for issuance under the 2025 ESPP. In addition, the number of shares of common stock reserved for issuance under the 2025 ESPP will automatically increase on January 1 of each year for a period of 10 years, beginning on January 1, 2026 and continuing through and including January 1, 2035, by an amount equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 227,944 shares; provided that before the date of any such increase, the Company's board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). The number of shares reserved for issuance under the 2025 ESPP was increased by 111,816 shares effective January 1, 2026 in accordance with the provisions of the 2025 ESPP. The first offering

period began on January 16, 2026. During the nine months ended September 30, 2026, 10,013 shares of common stock were issued under the 2025 ESPP and as of September 30, 2026, 213,619 shares remained available for issuance under the 2025 ESPP.

Summary of Awards

During the nine months ended September 30, 2026, the Company granted 943,549 options with an aggregate grant-date fair value of $4.7 million and 1,042,716 RSUs with an aggregate grant-date fair value of $6.1 million to employees of the Company.

Stock-based compensation expense

Stock-based compensation expense was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expenses	$ 270	$ 10,005	$ 573	$ 10,062
General and administrative expenses	1,395	5,278	2,879	5,278
Total stock-based compensation expense	$ 1,665	$ 15,283	$ 3,452	$ 15,340

As of September 30, 2026, unrecognized stock-based compensation expense related to stock-based awards was $16.5 million, which is estimated to be recognized over a period of 3.1 years.

10. Commitments and Contingencies

Leases

There have been no material changes to the Company's lease agreements during the three or nine months ended September 30, 2026. For additional information on the Company's operating leases, see Note 8, *Leases*, of the Notes to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

Legal Proceedings and Other Contingencies

In connection with the merger, two actions were filed against the Company and its board of directors in the Supreme Court for the State of New York, County of New York, captioned Smith v. Ikena Oncology, Inc., et al., No. 653576/2025 (filed June 12, 2025) and Kent v. Ikena Oncology, Inc., et al., No. 653588/2025 (filed June 13, 2025) (collectively, the "Complaints"). The Complaints allege that the defendants filed or caused to be filed a materially incomplete and misleading registration statement with the SEC and asserts claims under New York common law for negligent misrepresentation and concealment and negligence. In addition, the Company and its board of directors have received five additional demands from purported stockholders seeking additional disclosures in the registration statement (collectively, the "Demands"). On February 27, 2026, the Complaints were voluntarily dismissed and the Company has received no additional outreach from the purported stockholders who sent the Demands.

Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Regardless of outcome, litigation can have an adverse impact on the business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2026.

Licensing Agreements with HUTCHMED Limited

Upon consummation of the Merger in July 2025, the Company became the successor of the Collaboration, Option and License Agreement, as amended (the "Hutchmed Agreement") between Legacy Inmagene and HUTCHMED Limited (formerly known as Hutchison MediPharma Limited) ("Hutchmed"). Under the terms of the Hutchmed Agreement, Legacy Inmagene received an exclusive, royalty-free, worldwide license to perform research and development and for use in regulatory filings related to the licensed compounds (the "Licensed Compounds"). Further, on a Licensed Compound-by-Licensed Compound basis, Hutchmed granted Legacy Inmagene the exclusive option to the worldwide license with the right to sublicense to develop, manufacture and commercialize the licensed compound, with Hutchmed retaining first right to co-commercialization in mainland China (each a "License Option"). In April 2023, Legacy Inmagene entered into an amendment to the Hutchmed Agreement which terminated portions of the Hutchmed Agreement related to one of the compounds, and extended Legacy Inmagene's deadline for License Option exercise by an additional year to allow time for additional research to be performed on two of the remaining targets. On October 16, 2023, Legacy Inmagene exercised the License Option for (a) anti-OX40 mAb, and (b) the BTK (Bruton tyrosine kinase) inhibitor. Upon exercise of the License Option, Legacy Inmagene acquired an exclusive, worldwide, royalty-bearing license with the right to sublicense through multiple tiers, under certain patents and know-how controlled by Hutchmed and Hutchmed's right, title and interest in the joint intellectual property to develop, manufacture and commercialize any product that contains, incorporates, or otherwise includes the Licensed Compound (the "Licensed Products").

Hutchmed is eligible to receive up to $92.5 million for each Licensed Product upon the achievement of various development and regulatory milestones. Additionally, Hutchmed is eligible to receive up to $135.0 million for each Licensed Compound upon the achievement of various worldwide aggregate cumulative net sales milestones for the Licensed Products that contain such Licensed Compound and tiered royalty rates in the high-single-digit to low-tens percentages on a Licensed Compound-by-Licensed Compound basis for net sales of such Licensed Compounds worldwide, subject to reduction in certain circumstances. None of the payments under the Hutchmed Agreement are refundable. As of September 30, 2026, the Company has not met any of the milestones.

In connection with the Non-OX40 Divestiture (see Note 1), the BTK inhibitor program was initially sublicensed to BuyCo. Thereafter, pursuant to a novation agreement, BuyCo became the direct licensee of the BTK inhibitor program from Hutchmed. The Company continues to actively develop the anti-OX40 mAb program.

Legacy Collaborative Arrangements

Other collaboration agreements and programs that Legacy Inmagene was a party to were divested in connection with the Non-OX40 Divestiture as described in Note 1 and the Company has no further obligations under such agreements.

11. Net Loss per Share

The Company recast its basic and diluted earnings per share computation for the three and nine months ended September 30, 2025 for the effect of the exchange ratio of 0.0030510 resulting from the close of the Merger on July 25, 2025.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (15,620)	$ (24,779)	$ (36,417)	$ (38,441)
Less: accretion of redeemable convertible preferred shares	—	(846)	—	(7,046)
Net loss attributable to common stockholders - basic and diluted	$ (15,620)	$ (25,625)	$ (36,417)	$ (45,487)
Denominator:				
Weighted-average common stock outstanding	11,840,675	8,526,781	11,445,997	3,808,867
Weighted-average Series A convertible preferred shares outstanding	—	270,345	—	750,707
Weighted-average common shares outstanding under the pre-funded warrants	5,282,016	—	3,407,555	—
Total weighted-average shares outstanding	17,122,691	8,797,126	14,853,552	4,559,574
Net loss per share attributable to common stockholders - basic and diluted	$ (0.91)	$ (2.91)	$ (2.45)	$ (9.98)

For purposes of calculating net loss per share, the Company considered the Legacy Inmagene Series A Convertible Preferred Shares to represent a class of common stock. As a result, basic and diluted net loss per share attributable to common stockholders include Legacy Inmagene Series A Convertible Preferred Shares for the periods such shares were outstanding.

The Company issued and sold pre-funded warrants in April 2026 (see Note 8). The shares of common stock underlying the pre-funded warrants are included in the calculation of basic and diluted net loss per share because they are considered shares issuable for little or no consideration under ASC 260, Earnings Per Share.

The following shares of potentially dilutive securities outstanding as of period end were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	September 30,	
	2026	2025
Options to purchase common stock	1,771,741	1,020,222
Unvested restricted stock units	1,287,711	—
Total potentially dilutive shares	3,059,452	1,020,222

12. Segment Information

The Company operates and manages its business as a single operating and reportable segment for the purpose of assessing performance and making operating decisions. Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the Company's chief operating decision maker, or decision-making group (the "CODM"), in deciding how to allocate resources and assess performance. The Company's chief executive officer, who is the CODM, reviews the Company's financial information on an aggregated basis for purposes of evaluating financial performance and allocating resources. The CODM assesses operating performance as compared to planned activities for the operating segment and decides how to allocate resources based on net loss that is reported on the consolidated statement of operations and comprehensive loss.

As a single reportable segment entity, the Company's segment performance measure is net loss. In addition to the significant expense categories included within consolidated net loss presented in the condensed consolidated statements of operations and comprehensive loss, the CODM is regularly provided the following significant segment financial information to assist in segment performance evaluation, resource allocation, and decision-making (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development:				
Direct research and development expenses:				
Program costs	$ 9,997	$ 4,028	$ 19,893	$ 12,016
Unallocated research and development expenses:				
Personnel-related	936	1,123	3,116	2,771
Stock-based compensation	270	10,005	573	10,062
Other	67	—	318	—
Total research and development expenses	$ 11,270	$ 15,156	$ 23,900	$ 24,849
General and administrative:				
Personnel-related	$ 1,449	$ 1,046	$ 4,978	$ 2,374
Stock-based compensation	1,395	5,278	2,879	5,278
Consulting and professional services	1,733	1,863	5,206	4,164
Facilities-related and other	1,462	2,849	4,209	3,680
Total general and administrative expenses	$ 6,039	$ 11,036	$ 17,272	$ 15,496

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

You should read the following discussion and analysis of our financial condition and results of operations together with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report and the audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our annual report on Form 10-K, filed with the SEC on March 10, 2026. The following discussion contains forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this Quarterly Report, particularly in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." We do not intend, and undertake no obligation, to update these forward-looking statements, except as required by law.

Overview

We are a clinical-stage biopharmaceutical company developing therapeutics for patients with immunological, autoimmune and inflammatory diseases. Our lead asset, IMG-007, recently named olevaprubart, is a non-depleting anti-OX40 monoclonal antibody that binds specifically to OX40 receptor on activated T cells to block receptor binding to OX40 ligand ("OX40L"). Olevaprubart is being developed to potentially treat multiple autoimmune and inflammatory diseases and disorders, with initial evaluation in AD and AA. OX40 signaling is thought to be important in driving the pathogenesis of a spectrum of immunological, autoimmune and inflammatory diseases, including additional dermatological diseases, respiratory, gastrointestinal, and rheumatic diseases. Olevaprubart is initially being developed for the treatment of AD and AA, and we believe it has further "pipeline within a product" potential. We may explore additional indications with olevaprubart such as asthma, rheumatoid arthritis, and hidradenitis suppurativa, among others.

A multi-country Phase 2b dose-finding AD study began in 2025 and is progressing under an amended protocol. The amendment enables optimized dosing of patients with a range of dose exposures. Topline data from the Phase 2b clinical trial is expected in the fourth quarter of 2027.

We expect to initiate a Phase 2 study in AA by the end of 2026. The study objectives will be characterization of the benefit-risk of olevaprubart and dose selection for future pivotal studies. We expect to have initial data from the Phase 2 study in AA in 2028.

In April 2026, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors"), including existing investors, pursuant to which we issued and sold pre-funded warrants to purchase up to 5,770,335 shares of voting common stock (the "Warrant Shares") at $0.001 per share, in a private placement transaction (the "Private Placement") at a purchase price of $5.199 per Warrant Share to the Investors for gross proceeds of $30.0 million. In connection with a registration rights agreement entered into with the Investors to grant the Investors customary registration rights, we filed a registration statement on Form S-3 with the SEC for the resale of the Warrant Shares, which registration statement was declared effective on August 11, 2026.

Reverse Merger, Non-OX40 Divestiture and 2025 PIPE Financing

On July 25, 2025, we completed the Merger. In connection with the completion of the Merger, we changed our name from "Ikena Oncology, Inc." to "ImageneBio, Inc." and the business conducted by us became primarily the business conducted by Legacy Inmagene.

On July 25, 2025, immediately prior to consummation of the Merger, we consummated the divestiture of the non-IMG-007 business related assets, business and operations (the "Non-OX40 Business") controlled by us immediately prior to the Merger (the "Non-OX40 Divestiture") by selling and transferring (including via sublicense) all of the Non-OX40 Business to Miragene Inc., a newly formed private company and our wholly owned subsidiary ("Miragene"). As part of the Non-OX40 Divestiture, Miragene Co, a newly formed private company and related party ("BuyCo") held by the holders of outstanding Legacy Inmagene Shares prior to the Merger, purchased Miragene from us in exchange for a promissory note in the amount of $8.9 million. Any payments made under the promissory note to us will be distributed to Legacy Inmagene CVR holders as Legacy Inmagene CVR Payments.

As a result of the Non-OX40 Divestiture, IMG-007 became the only product candidate we have in clinical development. In connection with the Non-OX40 Divestiture, we entered into a Transition Services Agreement (the "Transition Services Agreement"), dated July 25, 2025, with Miragene for the provision of certain transitional services related to the ongoing IMG-007 program.

Concurrently with the execution of the Merger Agreement, and in order to provide us with additional capital for the IMG-007 program, Ikena entered into subscription agreements with certain accredited investors, pursuant to which, immediately following the closing of the Merger, Ikena issued and sold an aggregate of 2,508,337 shares of common stock in a private placement at a price of $29.90 per share for aggregate gross proceeds of $75.0 million (the "2025 PIPE Financing").

See Item 1 of Part I "Financial Statements—Note 1 – *Organization*" for additional information.

Impact of General Economic Risk Factors on the Company's Operations

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including elevated and fluctuating inflation, fluctuating interest rates, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy, changes in government regulatory policies, or government budget dynamics (particularly in the pharmaceutical and biotech areas), geopolitical factors, and supply chain disruptions. While we are closely monitoring the impact of the current macroeconomic and geopolitical conditions on all aspects of our business, including the impacts on participants in any future clinical trials and our employees, suppliers, vendors and business partners and our future access to capital, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources.

Components of Results of Operations

License Revenue

We have not generated any revenue from product sales. Our revenue has been derived from license payments under collaboration and license agreements, which were divested in connection with the Non-OX40 Divestiture described above.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses**.**

Research and Development

Research and development expenses consist of costs incurred in connection with the research and development of our programs. These expenses primarily include:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), consultants, members of our scientific and therapeutic advisory boards, and contract manufacturing organizations ("CMOs");
- employee-related expenses, including salaries, benefits, travel, and stock-based compensation; and
- license and sub-license fees.

We expect to continue to incur significant expenses for the foreseeable future as we seek to advance olevaprubart through clinical development, including in additional indications, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance olevaprubart or any future product candidate to regulatory approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation, for individuals in our executive, finance, human resources, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to corporate matters and patent-related expenses, allocated facilities and overhead costs, including insurance and information technology, and professional and consulting fees associated with accounting, audit, tax and investor and public relations. We expect our general and administrative expenses to increase over the next several years as we continue our research and development activities, prepare for potential commercialization of olevaprubart and any future product candidates, as well as expand our operations and operate as a public company.

Other Income (Expense)

Interest Income, Net

Interest income, net consists of interest earned on cash, cash equivalents and marketable securities, including amortization of purchase premiums and accretion of discounts of marketable securities. Interest income, net for 2025 also included interest expense on a term loan from Ikena that was settled as part of the Merger. We no longer incur interest expense.

Other Income, Net

Other income, net consists of miscellaneous income (expense) unrelated to our core operations.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
License revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	11,270	15,156	(3,886)
General and administrative	6,039	11,036	(4,997)
Total operating expenses	17,309	26,192	(8,883)
Loss from operations	(17,309)	(26,192)	8,883
Other income (expense):			
Interest income, net	1,189	1,055	134
Other income, net	520	284	236
Total other income, net	1,709	1,339	370
Loss before income taxes	(15,600)	(24,853)	9,253
Income tax expense (benefit)	20	(74)	94
Net loss	$ (15,620)	$ (24,779)	$ 9,159

License Revenue

We did not have license revenue for either of the three months ended September 30, 2026 or 2025. Following the Non-OX40 Divestiture, we no longer generate revenue under license and collaboration agreements.

Research and Development Expenses

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

	Three Months Ended September 30,		
	2026	2025	Change
Direct research and development expenses:			
Program costs	$ 9,997	$ 4,028	$ 5,969
Unallocated research and development expenses:			
Personnel-related	936	1,123	(187)
Stock-based compensation	270	10,005	(9,735)
Other	67	—	67
Total research and development expenses	$ 11,270	$ 15,156	$ (3,886)

Research and development expenses for the three months ended September 30, 2026 were $11.3 million compared to $15.2 million for the three months ended September 30, 2025. The increase in program costs of $6.0 million was primarily due to increased clinical trial costs related to our Phase 2b dose-finding AD clinical trial that began in 2025 and the long-term extension (“LTE”) study that began in 2026 and an increase in manufacturing costs, partially offset by a decrease in clinical trial costs primarily as a result of the completion of our Phase 1 AA study. The decrease in stock-based compensation of $9.7 million was primarily due to stock-based compensation costs recognized during the three months ended September 30, 2025 related to Legacy Inmagene options and restricted stock units that vested upon completion of the Merger in July 2025.

General and Administrative Expenses

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

	Three Months Ended September 30,		
	2026	2025	Change
Personnel-related	$ 1,449	$ 1,046	$ 403
Stock-based compensation	1,395	5,278	(3,883)
Consulting and professional services	1,733	1,863	(130)
Facilities-related and other	1,462	2,849	(1,387)
Total general and administrative expenses	$ 6,039	$ 11,036	$ (4,997)

General and administrative expenses for the three months ended September 30, 2026 were $6.0 million compared to $11.0 million for the three months ended September 30, 2025. Decreased stock-based compensation expense of $3.9 million was primarily due to stock-based compensation expense recognized during the three months ended September 30, 2025 related to Legacy Inmagene options and restricted stock units that vested upon completion of the Merger in July 2025. Facilities-related and other also decreased by $1.4 million primarily due to an early termination fee for Ikena's Boston office lease and accelerated depreciation related to the Boston office.

Other Income (Expense)

Interest Income, Net

Interest income, net for the three months ended September 30, 2026 consisted of $1.2 million of interest income earned on our invested cash balances. Interest income, net for the three months ended September 30, 2025 consisted of $1.2 million of interest income earned on our invested cash balances, partially offset by interest expense of $0.1 million on a previously outstanding term loan from Ikena. Our term loan from Ikena was settled as part of the Merger and we no longer incur interest expense.

Other Income, Net

Other income, net for the three months ended September 30, 2026 and 2025 consisted primarily of sublease income.

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

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

	Nine Months Ended September 30,		
	2026	2025	Change
License revenue	$ —	$ 800	$ (800)
Operating expenses:			
Research and development	23,900	24,849	(949)
General and administrative	17,272	15,496	1,776
Total operating expenses	41,172	40,345	827
Loss from operations	(41,172)	(39,545)	(1,627)
Other income (expense):			
Interest income, net	3,566	742	2,824
Other income, net	1,235	288	947
Total other income, net	4,801	1,030	3,771
Loss before income taxes	(36,371)	(38,515)	2,144
Income tax expense (benefit)	46	(74)	120
Net loss	$ (36,417)	$ (38,441)	$ 2,024

License Revenue

License revenue for the nine months ended September 30, 2025 related to non-OX40 programs. Following the Non-OX40 Divestiture, we no longer generate revenue under license and collaboration agreements.

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2026	2025	Change
Direct research and development expenses:			
Program costs	$ 19,893	$ 12,016	$ 7,877
Unallocated research and development expenses:			
Personnel-related	3,116	2,771	345
Stock-based compensation	573	10,062	(9,489)
Other	318	—	318
Total research and development expenses	$ 23,900	$ 24,849	$ (949)

Research and development expenses for the nine months ended September 30, 2026 were $23.9 million compared to $24.8 million for the nine months ended September 30, 2025. The increase in program costs of $7.9 million was primarily due to increased clinical trial costs related to our Phase 2b dose-finding AD study that began in 2025 and the LTE study that began in 2026, partially offset by a decrease in clinical trial costs primarily due to the completion of our Phase 1 AA study. Decreased stock-based compensation expense of $9.5 million was due primarily to stock-based compensation costs recognized during the nine months ended September 30, 2025 related to Legacy Inmagene options and restricted stock units that vested upon completion of the Merger in July 2025.

General and Administrative Expenses

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

	Nine Months Ended September 30,		
	2026	2025	Change
Personnel-related	$ 4,978	$ 2,374	$ 2,604
Stock-based compensation	2,879	5,278	(2,399)
Consulting and professional services	5,206	4,164	1,042
Facilities-related and other	4,209	3,680	529
Total general and administrative expenses	$ 17,272	$ 15,496	$ 1,776

General and administrative expenses for the nine months ended September 30, 2026 were $17.3 million compared to $15.5 million for the nine months ended September 30, 2025. Increases in personnel-related expenses of $2.6 million were primarily due to overall compensation increases and retention costs. Decreased stock-based compensation expense of $2.4 million was due primarily to stock-based compensation costs recognized during the nine months ended September 30, 2025 related to Legacy Inmagene options and restricted stock units that vested upon completion of the Merger in July 2025. Consulting and professional services costs increased by $1.0 million primarily due to an increase in legal costs related to intellectual property and general corporate activity. Facilities-related and other also increased by $0.5 million primarily due to increased facilities costs primarily related to an Ikena lease that expires in April 2027 and increases in insurance costs and other costs to support our operations as a public company, partially offset by an early termination fee for Ikena's Boston office lease and accelerated depreciation related to the Boston office.

Other Income (Expense)

Interest Income, Net

Interest income, net for the nine months ended September 30, 2026 consisted of $3.6 million of interest income earned on our invested cash balances. Interest income, net for the nine months ended September 30, 2025 consisted of $1.2 million of interest income earned on our invested cash balances, partially offset by interest expense of $0.5 million on a previously outstanding term loan from Ikena. Our term loan from Ikena was settled as part of the Merger and we no longer incur interest expense.

Other Income, Net

Other income, net for the nine months ended September 30, 2026 and 2025 consisted primarily of sublease income.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have devoted substantially all of our resources to advancing the development of our portfolio of programs, organizing and staffing, business planning, raising capital, and providing general and administrative support for these operations. We have incurred recurring losses and negative cash flows from operations since our inception. For the nine months ended September 30, 2026, we incurred a net loss of $36.4 million and, as of September 30, 2026, we had an accumulated deficit of $266.5 million. Prior to the Merger, we primarily funded our operations with proceeds from the sale and issuance of Legacy Inmagene preferred shares. Assets acquired in the Merger included $94.7 million of cash, cash equivalents and marketable securities. Additionally, we received gross proceeds of $75.0 million from the associated 2025 PIPE Financing. In April 2026, we received gross proceeds of $30.0 million from the Private Placement and incurred related issuance costs of $2.0 million. As of September 30, 2026, we had cash, cash equivalents and marketable securities of $126.6 million.

In August 2026, we entered into an at-the-market facility with Jefferies LLC ("Jefferies") under which we may offer and sell shares of our common stock from time to time through Jefferies acting as our sales agent (the "2026 ATM Facility"). On August 5, 2026, we filed a registration statement on Form S-3 with the SEC, which included a sales agreement prospectus under which we may offer and sell shares of our common stock having an aggregate offering price of up to $17.0 million pursuant to the 2026 ATM Facility. As of September 30, 2026, $17.0 million remained available for sale pursuant to the sales agreement prospectus.

Cash Flows

The following table sets forth a summary of cash flows (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (33,394)	$ (40,626)
Net cash used in investing activities	(1,171)	(4,450)
Net cash provided by financing activities	24,886	135,468

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $33.4 million, consisting primarily of our net loss of $36.4 million and net cash used by changes in our operating assets and liabilities of $0.9 million, partially offset by net non-cash charges of $4.0 million. Cash used by changes in our operating assets and liabilities primarily related to a $1.0 million increase in deposits and other non-current assets, including deposits for our clinical trials, and a $1.7 million decrease in operating lease liabilities, partially offset by a $0.9 million decrease in prepaid expenses and other current assets and a $0.9 million increase in accounts payable and accrued expenses and other current liabilities.

Net cash used in operating activities for the nine months ended September 30, 2025 was $40.6 million, consisting primarily of our net loss incurred during the period of $38.4 million and net cash used by changes in our operating assets and liabilities of $18.3 million, partially offset by non-cash charges of $16.1 million, including stock-based compensation expense of $15.3 million. Cash used by changes in our operating assets and liabilities primarily related to a $12.1 million decrease in accounts payable and accrued expenses and other current liabilities, a $3.6 million increase in prepaid expenses and other current assets, a $1.3 million increase in deposits and other non-current assets primarily related to deposits for our clinical trials, a $0.7 million decrease in operating lease liabilities, and a $0.7 million decrease in deferred revenue.

Changes in prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities are generally due to the advancement of our research and development programs and the timing of vendor invoicing and payments.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 was $1.2 million consisting of purchases of available-for-sale securities of $24.6 million, partially offset by maturities of available-for-sale securities of $23.4 million.

Net cash used in investing activities for the nine months ended September 30, 2025 was $4.5 million consisting of payments of $5.2 million made in connection with the Non-OX40 Divestiture and purchases of available-for-sale securities of $1.5 million, both partially offset by maturities of available-for-sale securities of $2.3 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 of $24.9 million consisted primarily of net cash provided by the issuance of pre-funded warrants for common stock of $28.0 million, partially offset by the payment of issuance costs incurred in 2025 in connection with the reverse recapitalization of $3.3 million.

Net cash provided by financing activities for the nine months ended September 30, 2025 was $135.5 million, consisting primarily of proceeds of $71.1 million from issuance of common stock for the 2025 PIPE Financing, cash acquired of $54.6 million in connection with the Merger, and $15.0 million of proceeds from the Term Loan, all partially offset by the payment of $5.3 million of offering costs in connection with the Merger.

Funding Requirements

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $126.6 million. We believe that our cash, cash equivalents and marketable securities are sufficient to support operations through at least the next 12 months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report.

We will need substantial additional funding to support our operating activities as we advance our potential product candidates through development, seek regulatory approval, and prepare for and, if any of our product candidates are approved, proceed to commercialization. Because the length of time and activities associated with successful development of olevaprubart and any future product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities. Our future funding requirements will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of discovery, preclinical studies and clinical trials of olevaprubart and any future product candidates;
- the costs and timing of manufacturing for olevaprubart and any future product candidates, including if we develop our own manufacturing capabilities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;
- the cost of obtaining, maintaining and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize olevaprubart and any future product candidates for which we may obtain regulatory approval;
- the timing and amount of royalty, milestone or other payments made to our current or future suppliers, collaborators or licensors;
- the timing and amount of the milestone or other payments made to us under any future collaboration or licensing agreements;
- costs associated with growing our workforce and retaining and motivating our employees;
- the initiation, progress, timing and results of our commercialization of olevaprubart and any future product candidates, if approved for commercial sale;
- costs associated with any products or technologies that we may in-license or acquire;
- the costs associated with being a public company; and
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, including under our 2026 ATM Facility, debt financings and license and collaboration agreements. Adequate funding may not be available to us on acceptable terms, or at all. If we are unable to obtain additional funding, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate some or all of our planned operations, which may have a material adverse effect on our business, financial condition, results of operations, and ability to operate as a going concern.

For more information as to the risks associated with our future funding needs, see the section titled "Risk Factors—Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital."

Contractual Obligations and Other Commitments

There have been no material changes to our cash commitments from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Critical Accounting Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and related disclosures. We evaluate our estimates on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2025 included in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 – *Summary of Significant Accounting Policies* to our unaudited condensed consolidated financial statements included in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026, the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures were not effective as a result of a material weakness in internal control over financial reporting as described below.

Material Weakness in Internal Control over Financial Reporting

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. We did not design and maintain effective controls related to the period-end financial reporting process to ensure adequate segregation of duties, including controls related to account reconciliations and journal entries. Specifically, certain personnel have incompatible duties including the ability to (i) create and post manual journal entries without an independent review and (ii) prepare and review account reconciliations. The material weakness did not result in a misstatement to the consolidated financial statements.

However, this material weakness could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Management's Plan to Remediate the Material Weakness

To remediate the material weakness, we plan to design and implement control activities in response to the risks posed as a result of the lack of segregation of duties related to journal entries and account reconciliations, including general controls over information systems. The material weakness will not be considered remediated until management completes the design and implementation of the measures described above, the controls operate for a sufficient period of time and management has concluded, through testing, that the controls are effective. The measures we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not remediate the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Information with respect to legal proceedings is included in Note 10 - *Commitments and Contingencies* of the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report, which is incorporated herein by reference.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. In addition to the risk and uncertainties described under the section titled "Special Note Regarding Forward-Looking Statements," the risks and uncertainties described below should be carefully considered, together with all of the other information contained in this Quarterly Report, including our condensed consolidated financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations", before deciding to invest in our common stock. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our common stock could decline, and our stockholders could lose all or part of their investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business or results of operations.

Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage biopharmaceutical company with a limited operating history. Our operations to date have focused on organizing and staffing our operations, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of olevaprubart. We have not yet demonstrated an ability to successfully manufacture, obtain marketing approvals for or commercialize olevaprubart. We have no products approved for commercial sale and have not generated any revenue from product sales. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We are focused on the discovery and development of innovative drugs for the treatment of various immunological, autoimmune and inflammatory diseases. Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. As a result, any assessment of our future performance or viability is subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and the significant risk that product candidates will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. For the nine months ended September 30, 2026 and the year ended December 31, 2025, our net losses were $36.4 million and $45.3 million, respectively. As of September 30, 2026, we had an accumulated deficit of $266.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance olevaprubart through clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance olevaprubart or any future product candidate to regulatory approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any revenue from the commercialization of any approved products or achieve or maintain profitability. Our expenses will also increase substantially as we operate as a public company following the Merger and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

We cannot generate any revenue from product sales unless and until we obtain regulatory approvals for olevaprubart and any future product candidates in our desired jurisdictions, successfully manufacture olevaprubart and any future product candidates, and successfully build a commercial organization. These activities will require substantial investment and significant marketing efforts. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, the competent authorities of individual EU Member States or comparable foreign regulatory authorities to perform additional preclinical studies and clinical trials or to modify any of our manufacturing processes or make other changes to olevaprubart or any future product candidates than those that we currently anticipate. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any particular quarterly or annual period should not be relied on as indications of future operating performance. If we are unable to develop, obtain regulatory approval, and successfully commercialize olevaprubart or any future product candidate either alone or with collaborators, or if revenue from olevaprubart and any future product candidates that receive regulatory approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our securities will be adversely affected.

We will need to obtain substantial additional funding to complete the development and any commercialization of olevaprubart and any future product candidates, which may cause dilution to our stockholders. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect to spend substantial amounts to advance olevaprubart and any future product candidate into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize olevaprubart and any future product candidate, if approved. In addition, as olevaprubart progresses through development and toward commercialization, we will need to make certain milestone payments to HUTCHMED Limited (formerly known as Hutchison MediPharma Limited) ("Hutchmed") under a collaboration, option and license agreement with Hutchmed (as amended, the "Hutchmed Agreement") and tiered royalties from commercial sales of olevaprubart, if approved. We will require additional capital to support our product development efforts and operations, which we may raise through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of olevaprubart and any future product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Our operations have consumed significant amounts of cash since inception. Because the length of time and activities associated with successful development of olevaprubart and any future product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities.

Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of discovery, preclinical studies and clinical trials of olevaprubart and any future product candidates;
- the costs and timing of manufacturing for olevaprubart and any future product candidates, including if we develop our own manufacturing capabilities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;
- the cost of obtaining, maintaining and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize olevaprubart and any future product candidates for which we may obtain regulatory approval;
- the timing and amount of royalty, milestone or other payments made to our current or future suppliers, collaborators or licensors;
- the timing and amount of the milestone or other payments made to us under any future collaboration or licensing agreements;

- costs associated with growing our workforce and retaining and motivating our employees;
- the initiation, progress, timing and results of our commercialization of olevaprubart and any future product candidates, if approved for commercial sale;
- costs associated with any products or technologies that we may in-license or acquire;
- the costs associated with being a public company; and
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, including through our 2026 ATM Facility, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Discovery and Development of our Product Candidates

Our business is entirely dependent on the success of olevaprubart for the treatment of AD and AA and for other potential indications.

On July 25, 2025, immediately prior to consummation of the Merger, Legacy Inmagene consummated the Non-OX40 Divestiture. Accordingly, our business is entirely dependent on the success of olevaprubart for the treatment of AD and AA and other potential indications. Olevaprubart is currently in Phase 2 development for the treatment of moderate-to-severe AD. We may also develop olevaprubart for other immunological, autoimmune and inflammatory diseases such as asthma, rheumatoid arthritis, and hidradenitis suppurativa. We cannot give any assurance that we will generate preclinical, clinical or other data for olevaprubart for the treatment of AD, AA or other immunological, autoimmune and inflammatory diseases sufficiently supportive to receive regulatory approval, which will be required before olevaprubart can be commercialized. We may, among other things, experience difficulties with patient recruitment, enrollment and retention, quality and provision of materials and supplies necessary to manufacture sufficient quantities of drug product to meet our current or future preclinical study and clinical trial needs on a timely basis, or safety signals or pharmacodynamic, pharmacokinetic or efficacy data that does not align with our target profile for olevaprubart. Olevaprubart will require significant further clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of olevaprubart, which may never occur. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize olevaprubart, we may not be able to generate sufficient revenue to continue our business and our business would be materially harmed.

Interim, topline and preliminary data from our preclinical studies or clinical trials that we announce or publish from time to time may not be predictive of future results and may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes to the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our preclinical studies, clinical trials or planned clinical trials, which is based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline 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, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical

outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline 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, approvability or commercialization of olevaprubart or any future product candidate, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others including comparable foreign regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, olevaprubart or any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Moreover, results from previous preclinical studies or clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Olevaprubart or any future product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies of such product candidates or having successfully advanced through initial clinical trials.

Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

The clinical trials and manufacturing of olevaprubart and any future product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market olevaprubart and any future product candidates. Before obtaining regulatory approvals for the commercial sale of any of olevaprubart or any future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidates are both safe and effective for use in each target indication. In particular, because olevaprubart is subject to regulation as a biological drug product, we will need to demonstrate that it is safe, pure and potent for use in its target indications. Olevaprubart and future product candidates must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and takes many years to complete, and is subject to uncertainty. Our planned clinical trials may not be conducted as planned or completed on schedule, if at all. Delays and failures can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, their results may not support the safety and effectiveness of olevaprubart or any future product candidates for their targeted indications or support continued clinical development of such product candidates. Our future clinical trial results may not be successful.

In addition, even if our planned trials are successfully completed, the FDA or comparable foreign regulatory authorities may not interpret the results as we do, and more trials could be required before we submit olevaprubart or any future product candidates for approval. To the extent that the results of the 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 trials in support of potential approval of olevaprubart or any future product candidates.

To date, we have not completed any pivotal clinical trials required for the approval of olevaprubart. We may experience delays in conducting any clinical trials, and we do not know whether our clinical trials will begin on time, will need to be redesigned, will recruit and enroll patients on time or have data readouts or be completed on schedule, or at all. Events that may prevent successful or timely commencement, readouts, and completion of clinical development and preclinical studies include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials, or failure to do so;
- delays in reaching agreement with the FDA, or other comparable foreign regulatory authorities as to the design or implementation of our clinical trials, or failure to do so;
- delays in or failure to obtain regulatory approval to commence a clinical trial;
- delays in or failure to reach an agreement on acceptable terms with clinical trial sites or prospective CROs the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;

- delays in or failure to obtain institutional review board ("IRB") approval or positive ethics committee opinion at each site;
- delays in or failure to recruit suitable patients to participate in a clinical trial;
- delays in or failure to have patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the FDA's Good Clinical Practice ("GCP") requirements, or applicable regulatory guidelines in other countries;
- delays or failure due to restrictions or other mandated requirements imposed by FDA or other regulatory bodies on the conduct of the clinical development program based on either internal or external data, such as emerging data with other molecules, either in development or approved, that target the same immunological pathway as olevaprubart;
- the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to olevaprubart or any future product candidates;
- failure in addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with olevaprubart or any future product candidate that are viewed to outweigh its potential benefits;
- failure to add a sufficient number of clinical trial sites; or
- failure to manufacture sufficient quantities of olevaprubart or any future product candidates for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize olevaprubart or any future product candidates or significantly increase the cost of such trials, including:

- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of olevaprubart or any future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of olevaprubart or any future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- the ability to monitor patients adequately during or after treatment;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of olevaprubart or any future product candidates for various reasons, including non-compliance with regulatory requirements, a finding that olevaprubart or any future product candidates have undesirable side effects or other unexpected characteristics, a finding that the participants are being exposed to unacceptable health risks;
- adverse events suffered by clinical trial participants that may ultimately be determined to be unrelated to olevaprubart or any future product candidates;
- adverse events and safety information from other clinical trials of other product candidates also targeting OX40;
- the cost of clinical trials of olevaprubart or any future product candidates may be greater than we anticipate and we may elect not to cover the costs;
- the supply or quality of olevaprubart or any future product candidates or other materials necessary to conduct clinical trials of olevaprubart or any future product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving olevaprubart or any future product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of olevaprubart or any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of olevaprubart or any future product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for olevaprubart or any future product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB") for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension, variation or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Olevaprubart will require extensive clinical testing before we are prepared to submit a biologics license application ("BLA") or marketing authorization application ("MAA") for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for olevaprubart or any future product candidates and submit a BLA or MAA for regulatory approval of olevaprubart or any future product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, or other comparable foreign regulatory authorities on our clinical development program, and the FDA or such other comparable foreign regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development of olevaprubart or any future product candidates.

We also cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of olevaprubart or any future product candidates could be harmed, and our ability to generate revenue from olevaprubart or any future product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of olevaprubart or any future product candidates.

Olevaprubart or any future product candidates may cause serious adverse events ("SAEs") or undesirable side effects or have other properties that may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Manipulation of the immune system via therapeutic agents can result in a spectrum of immunosuppression depending on the target and the disease being treated. In general terms immunosuppression has been associated with increased risk of infection and, with long term immunosuppression, malignancies. The risk of these types of events is dependent both on the breadth of immunosuppression as well as the disease and population in which it is being used.

As with all protein-based therapies administered either intravenously or subcutaneously there is also the risk of injection site reactions and systemic hypersensitivity reactions, with cases of anaphylaxis reported with some such agents. The incidence and severity of these reactions vary depending on the characteristics of both the therapeutic agent, its target, and the vehicle solution in which the therapy is administered.

When considering other therapies that target the OX40/OX40L pathway, infections including serious infections, injection site reactions, chills and pyrexia, hypersensitivity reactions, oral and gastrointestinal ulceration, and malignancies including Kaposi Sarcoma have been reported. To date, a causal association between the therapies targeting the pathway and the events has not been established.

There may be undesirable side effects and adverse events associated with olevaprubart or any future product candidates. Undesirable side effects or adverse events that may be caused by olevaprubart or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

In addition, adverse safety findings or events associated with other therapies targeting the OX40/OX40L pathway, even if not observed in clinical trials of olevaprubart, could negatively affect the development of olevaprubart. Such findings or events could cause regulatory authorities to impose additional requirements on our clinical trials, including enhanced safety monitoring, additional studies or clinical holds, and could adversely affect patient enrollment and retention, delay or prevent regulatory approval, or otherwise negatively impact the development and potential commercialization of olevaprubart.

While the data reported to date from our Phase 1 and Phase 2a clinical trials indicate that olevaprubart was generally well tolerated, there remains a risk that clinical trial results could reveal high and unacceptable severity and prevalence of previously unreported side effects or unexpected characteristics. Any such findings could cause delays in completion or cancellation of our clinical trials or require us to abandon or limit our development of olevaprubart.

If unacceptable treatment-related side effects or deaths arise in the development of olevaprubart or any future product candidates, we, the FDA, the IRBs or ethics committees at the institutions in which our studies are conducted, DSMB or comparable foreign regulatory authorities could suspend, vary or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of olevaprubart or any future product candidates for any or all targeted indications. Further undesirable side effects, dose-limiting toxicity events, or deaths in clinical trials with olevaprubart or any future product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, dose de-escalation, or additional protocol amendments, or otherwise to delay or deny approval of olevaprubart or any future product candidates for any or all targeted indications. Treatment-related side effects could also affect site initiation, patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays or complications.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for olevaprubart or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trials' conclusion as required by the FDA or other comparable foreign regulatory authorities. We may experience difficulty in patient enrollment in our clinical trials for a number of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will not remain in the trial through the completion of evaluation.

Competing with numerous ongoing trials and established therapies poses a challenge in recruiting patients. Our clinical trials may also compete with other clinical trials of product candidates that are targeting the same indications as olevaprubart or any future product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Additionally, the number of qualified clinical investigators is limited, so we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Recent announcements of clinical trial plans by various companies targeting immunological, autoimmune and inflammatory diseases could intensify future competition for investigators and patients. Failure to enroll a sufficient number of patients promptly could lead to delays or failure in completing our trials, hindering the development and commercialization of olevaprubart or any future product candidates within certain patient subgroups or altogether.

We may not identify or discover other product candidates and may fail to capitalize on product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to develop olevaprubart for the treatment of AD, AA and other potential indications targeting immunological, autoimmune and inflammatory diseases. We are seeking to do so through our internal research and development capabilities and may also explore additional strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different immunological, autoimmune and inflammatory diseases may require changes to the manufacturing processes of our CMOs or require us to identify new CMOs to manufacture our product candidates, which may slow down development of or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- choosing to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of immunological, autoimmune and inflammatory disease, and we may forego or delay pursuit of opportunities with certain product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for olevaprubart or any future product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or indication or fail to develop a potentially successful product candidate.

Our future preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or comparable foreign regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity and potency, or efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Olevaprubart is our only product candidate in clinical development. Before we can commence clinical trials for any future product candidates, we must complete extensive preclinical testing and studies that support Investigational New Drug applications ("INDs") in the United States and comparable applications outside the United States.

We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we may not submit INDs or similar applications for our preclinical programs within our anticipated timelines, if at all, and submission of INDs or similar applications may not result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design; and
- the FDA, or other comparable foreign regulatory authorities, not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for preclinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal for a future product candidate, the FDA may not accept the IND submissions as presented and thus, our clinical trial timelines could be delayed.

The affected populations for olevaprubart or any future product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for olevaprubart or any future product candidates.

We select the indications for the development of olevaprubart and any future product candidates based on a number of factors, including the estimated patient populations where we believe there is a meaningful addressable market opportunity. However, our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with olevaprubart or any future product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for olevaprubart or any future product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, alternative therapies and product pricing and reimbursement. For example, we intend to prioritize evaluation and seeking approval of olevaprubart for the treatment of AD and AA. We may also explore additional indications with olevaprubart such as asthma, rheumatoid arthritis, and hidradenitis suppurativa. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, our incidence and prevalence estimates should be viewed with caution. Further, our data and statistical information, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Disruptions to the operations of the FDA, the SEC, other U.S. governmental agencies or comparable foreign regulatory authorities caused by funding shortages, leadership changes, staffing cuts or other staffing shortages, along with uncertainty regarding the potential for new initiatives, laws, regulations, policies and guidance affecting our product candidates or other aspects of our business, could materially and adversely affect our business.

The ability of the FDA or other comparable foreign regulatory authorities to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, leadership changes, the ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, changes in statutes, regulations and policies that affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions, and other business disruptions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies, including the FDA. Changes and cuts in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion, or at all. If a government shutdown occurs or if the FDA or other federal agencies otherwise experience resource constraints, it could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, any future government shutdowns or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the current administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of olevaprubart or any future product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on olevaprubart or any future product candidates we develop and obtain the requisite regulatory approvals in the future. There is uncertainty as to whether we will be materially and negatively impacted by governmental orders, regulations, policies or guidance, or disruptions to the normal operations of government agencies.

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

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. 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 U.S. government has announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. Following that investigation, the President announced a proclamation which will impose 100% tariffs on certain patented pharmaceutical products and associated pharmaceutical ingredients. We are assessing the potential impact of the proclamation on our business.

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, several of our suppliers are located outside of the United States. For example, the active pharmaceutical ingredients ("APIs") and our olevaprubart product candidate are manufactured in China by a single manufacturer. The process uses proprietary know-how that would require expertise, expense and time to transfer, and we have no qualified backup. Our current supply is insufficient for the Phase 2b study, requiring additional manufacturing runs that may be delayed or more costly. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts. This dependence exposes us to geopolitical, trade, tariff, and sanctions risks, including actions that could disrupt or restrict work with Chinese entities. Any supply disruption, delay or cost increase could materially delay our trials and increase program costs.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with 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 in the future, 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 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 United States 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 may 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 prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report.

Risks Related to Manufacturing and Our Reliance on Third Parties

If we breach our current or future licenses or other intellectual property-related agreements for olevaprubart or any future product candidates or otherwise experience disruptions to our business relationships with our current or future licensors, we could lose the ability to continue the development and commercialization of our product candidates.

Unless and until we acquire and identify any new product candidates, our business will rely solely on our ability to develop and commercialize olevaprubart. We license rights to olevaprubart from Hutchmed pursuant to the Hutchmed Agreement and we also license certain rights from WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") to manufacture a component of olevaprubart pursuant to the license agreement (the "Cell Line License Agreement") and may enter into future licenses or other intellectual property-related agreements for olevaprubart or any future product candidates. Our licenses may not cover all intellectual property rights owned or controlled by our licensors or other third parties and relevant to olevaprubart or any future product candidates. If we have not obtained a license to all intellectual property rights owned or controlled by our licensors or other third parties that are relevant to olevaprubart or any future product candidate, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors breach such agreements, we may not be able to enforce such agreements against our licensors or their parent entity or affiliates. Under our Hutchmed Agreement, in exchange for licensing to us the right to develop and commercialize olevaprubart, Hutchmed will be eligible to receive from us certain milestone payments and tiered royalties from commercial sales of olevaprubart, if approved. In addition, under our Cell Line License Agreement, if we manufacture all of our commercial supplies of certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products") with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. Our license agreements also require us to comply with other obligations, including development and diligence obligations, providing certain information regarding our activities with respect to olevaprubart or maintaining the confidentiality of information we receive from our licensors. For example, under our Hutchmed Agreement, we are required to use commercially reasonable efforts to conduct the clinical, regulatory and other activities necessary to develop and commercialize olevaprubart in the U.S., EU and mainland China, and Hutchmed may terminate the agreement if we materially breach these obligations or if we fail to conduct any material development or commercialization with respect to olevaprubart for a continuous period of longer than 24 months, subject to certain exceptions. Any future license or intellectual property-related agreements may also contain similar provisions.

If we fail to meet any of our obligations under our license agreements, our licensors may have the right to terminate our licenses and, upon the effective date of such termination, have the right to re-obtain the licensed technology and intellectual property. If any of our licensors terminates any of our licenses, we will lose the right to develop and commercialize our applicable product candidates and other third parties may be able to market product candidates similar or identical to ours. In such case, we may be required to provide a grant back license to the licensors of our own intellectual property with respect to the terminated products. For example, if our Hutchmed Agreement terminates for any reason, we are required to grant Hutchmed an exclusive license to certain of our intellectual property rights that cover inventions and know-how owned or controlled by us or are used or applied as of the date of such termination in our development, manufacture or commercialization of olevaprubart or any future product candidates incorporating a licensed compound. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve the intellectual property rights licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our product candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such product candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our ability to generate revenue and achieve profitability from third party licensed product candidates also depends upon our ability to obtain and retain exclusivity on the licensed product candidates and related product candidates controlled by the licensor.

In addition, disputes may further arise regarding intellectual property subject to a license agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license 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 diligence obligations;
- the inventorship and 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.

Our licenses from Hutchmed and WuXi Biologics are limited to intellectual property rights owned or controlled by such licensors. To the extent any of our licensors lose ownership of or control over any of the intellectual property rights we license from them for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize our related product candidates. Any of the foregoing would have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize olevaprubart, or any other product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we experience disruptions to our business relationships with our licensors, we could lose the ability to continue to source, develop and commercialize olevaprubart or any future product candidates including ultimately losing our rights to such product candidates, which would have a material adverse effect on our business, financial conditions, results of operations and prospects.

We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain certain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.

We have licensed certain patent rights for olevaprubart from Hutchmed and may in the future license other patent rights from third parties. As a licensee of third parties, we may rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we may not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we may jointly own with certain of our licensors. We cannot be certain that these patents and patent applications have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover olevaprubart or other product candidates. If our licensors fail to prepare, prosecute or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize olevaprubart or other product candidates could be adversely affected.

Pursuant to the terms of the license agreements with certain of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents.

Even if we are permitted to pursue the enforcement or defense of our licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize olevaprubart or other product candidates could be adversely affected.

Our rights to develop and commercialize olevaprubart are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of olevaprubart. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize olevaprubart. As a result, we may not be able to prevent competitors from developing and commercializing competitive product candidates in territories included in all our licenses.

In addition, our licensors may have relied on third-party 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-license. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize olevaprubart. If such licenses are terminated, we may be required to seek alternative in-license arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, we may need to modify or cease the development, manufacture and commercialization of olevaprubart, and competitors would have the freedom to seek regulatory approval of and to market products identical to ours. 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. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We rely on third parties for the manufacture of olevaprubart for development, and expect to continue to do so for the foreseeable future. Our current and anticipated future dependence upon third parties for the manufacture of olevaprubart or any future product candidates increases the risk that we will not have sufficient quantities of olevaprubart or any future product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts and could impact future profit margins.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of olevaprubart and any future product candidates and related materials for development, as well as for commercial manufacture if olevaprubart or any future product candidates receives marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Our active pharmaceutical ingredients and drug product for olevaprubart are currently provided by a single-source supplier, WuXi Biologics, and we expect to rely on this supplier for the foreseeable future. Contract manufacturing organizations may become subject to legislation, trade restrictions, sanctions, tariffs and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities or otherwise substantially increase our manufacturing costs, thereby potentially disrupting the supply of material to us or requiring us to scale back our manufacturing activities. For example, the United States has recently passed legislation, namely the BIOSECURE Act, to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern" or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or equipment. Specifically, on December 18, 2025, the President signed the National Defense Authorization Act ("NDAA") for fiscal year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" ("BCC"); entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. The Office of Management and Budget will issue a list of BCCs no later than mid-December 2026. Companies designated as a BCC shall include (i) certain entities that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, (ii) companies that the Office of Management and Budget designates as a BCC based on certain criteria, and (iii) certain subsidiaries or parent or successor entities of the foregoing. There is a "safe harbor" provision in the BIOSECURE Act providing that the restrictions do not apply to equipment or services that were formerly but are no longer provided by a BCC, as well as a "grandfathering" provision providing that the prohibitions shall not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government.

In addition, the current administration's recent and evolving tariffs imposed on imports from China as well as China's retaliatory tariffs on U.S. goods may significantly increase our manufacturing costs and may further disrupt our supply chain and reduce our competitiveness in the marketplace. Any additional U.S. executive action, legislative action or potential sanctions with China or increased tariffs imposed on Chinese imports could materially impact entities that work with Chinese biotechnology companies. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Such disruption could have adverse effects on the development of our product candidates.

Furthermore, we do not have complete control over all aspects of the manufacturing process and are dependent on our contract manufacturing partners for compliance with current Good Manufacturing Practice ("cGMP") regulations for manufacturing both drug substances and finished drug product. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and others, they will not secure and maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an applicable foreign authority does not approve these facilities for the manufacture of our product candidates or if the FDA or applicable foreign authority, withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market olevaprubart or any future product candidates, if approved. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements, and we may not be able to enter into new manufacturing arrangements on commercially reasonable terms or at all. In some cases, the technical skills or technology required to manufacture olevaprubart or any future product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a

feasible alternative may not exist. These factors would increase our reliance on our third-party manufacturers or require us to obtain a license from such manufacturers in order to have another third-party manufacture olevaprubart or any future product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any product produced by the new manufacturer is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and timelines, or at all, and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP or similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- reliance on single source manufacturers for drug substances and drug products;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- misappropriation of proprietary information, including our trade secrets and know-how;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We do not have any long-term commitments or supply agreements with our third-party manufacturers and may be unable to establish any supply agreements with our third-party manufacturers or do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantities at an acceptable cost, which may harm our business and results of operations.

In addition, under our Cell Line License Agreement with WuXi Biologics, if we manufacture all of our commercial supplies with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales manufactured by the manufacturer other than WuXi Biologics or its affiliates. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Some of our suppliers may experience disruption to their respective supply chain due to the effects of macroeconomic conditions, which could delay, prevent or impair our development or commercialization efforts.

We obtain certain active pharmaceutical ingredients, drug product and certain other research materials in countries affected by macroeconomic events and conditions, including inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, increasing financial market volatility and uncertainty, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. Supply chain disruptions and delays as a result of any new tariff policies or trade restrictions could also negatively impact our cost of materials and production processes. If we are unable to obtain our active pharmaceutical ingredients, drug product or other certain research materials in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and

conditions, the development, testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

We rely on third parties to conduct, supervise and monitor our discovery research, preclinical studies and clinical trials. If third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, the development of olevaprubart or any future product candidates may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not currently have the ability to independently conduct certain discovery research, preclinical studies and clinical trials for olevaprubart or any future product candidates. We rely on third parties, including CROs, academic institutions and clinical trial sites, to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely upon these third parties to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our third parties' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies or clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the third parties does not relieve us of our regulatory responsibilities.

We and our third parties will be required to comply with the good laboratory practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and applicable foreign authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we will rely on third parties to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the third parties does not relieve us of our regulatory responsibilities. If we or our third parties fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable foreign authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our third parties fail to comply with these regulations or fail to recruit a sufficient number of participants or ensure the collection of requisite data by clinical sites, we may be required to enroll additional participants or repeat clinical trials, which would delay the marketing approval process.

While we will have agreements governing their activities, our third parties will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition, and results of operations. If our relationship with these third parties terminates, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional third parties can involve substantial cost 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 occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships and contracts with our third parties, we may encounter challenges or delays in the future and we cannot make assurances that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or applicable foreign authorities. The FDA or applicable foreign authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or applicable foreign 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, refusal to accept or rejection, of

our marketing applications by the FDA or applicable foreign authorities and may ultimately lead to the denial of marketing approval of olevaprubart or any future product candidates.

We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of olevaprubart and any future product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to olevaprubart and any future product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We entered into the Hutchmed Agreement pursuant to which we collaborated with Hutchmed with respect to certain research and development activities, including related to olevaprubart. We may also form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to olevaprubart and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement.

Research and development collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of olevaprubart or any future product candidates or may elect not to continue or renew development or commercialization of such product candidates based on clinical trial results or changes in their strategic focus;
- collaborators may delay, provide insufficient resources to, or modify or stop clinical trials for olevaprubart or any future product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with olevaprubart or any future product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of olevaprubart or any future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of olevaprubart or any future product candidates; and
- collaborators may own or co-own intellectual property covering olevaprubart or any future product candidates that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for olevaprubart or any future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view olevaprubart or any future product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the

collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. For example, under our Hutchmed Agreement, Hutchmed has a right of first negotiation with respect to certain commercialization activities for our licensed products thereunder in mainland China.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biomedical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the Company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. In addition, we may face regulatory obstacles in completing such transactions. If we are unable to do so, we may have to reduce or delay the development of olevaprubart or any future product candidate, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop olevaprubart in one or more indications or any future product candidates or bring them to market and generate revenue.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. If collaborations occur, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue development of olevaprubart or any future product candidates. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such product candidates and our business and financial condition could suffer.

We may also seek to in-license third-party technologies to enhance olevaprubart or any future product candidates and we may be unable to in-license such rights at a reasonable cost, on reasonable terms or at all, which could harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology in order to establish or maintain our competitive position in the market. Any delays in entering into new collaborations or strategic partnership agreements related to olevaprubart or any future product candidates could delay the development and commercialization of such product candidates in certain geographies or indications or limit our ability to discover and develop new product candidates, which could harm our business prospects, financial condition, and results of operations.

Risks Related to Commercialization of Our Product Candidates

We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. If we successfully develop and commercialize olevaprubart or any future product candidate, we and any future collaborators will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of the entities developing and marketing potentially competing products have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and commercialization. Even if we are able to successfully develop and commercialize a product, our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are more convenient or are less expensive than our product.

We are developing olevaprubart for the treatment of moderate-to-severe AD. The key competitive factors affecting the success of olevaprubart, if approved, are likely to include efficacy, durability of response, safety and tolerability, convenience, presentation, price, the level of generic or biosimilar competition and the availability of reimbursement from government and other third-party payors. There are several advanced therapies approved for moderate-to-severe AD, such as DUPIXENT® (dupilumab), an IL-4Rα mAb marketed by Sanofi/Regeneron, ADBRY® (tralokinumab-ldrm), an IL-13 mAb marketed by Leo Pharma, EBGLYSS™ (lebrikizumab-lbkz), an IL-13 mAb marketed by Eli Lilly and NEMLUVIO® (nemolizumab-ilto), an IL-31R mAb marketed by Galderma Laboratories, L.P. There are several approved treatments that target JAK1 or JAK2 to treat AD, including

CIBINQO®(abrocitinib) marketed by Pfizer, RINVOQ® (upadacitinib) marketed by AbbVie in Europe, and OLUMIANT® (baricitinib) marketed by Eli Lilly. These approved products have all demonstrated clinically significant efficacy results.

Olevaprubart is currently the most advanced OX40/OX40L-targeting agent in development for AD. Rocatinlimab, a receptor-targeting anti-OX40 mAb designed to be T cell depleting was previously in development by Amgen and Kyowa Kirin and was discontinued in the first quarter of 2026. In the third quarter of 2026, Sanofi announced the discontinuation of development of amlitelimab, an OX40-ligand (OX40L) targeting mAb, in AD. In addition, there are several other OX40/OX40L targeting agents in the pipelines of various companies. These include monotherapies, free- or fixed-dose combinations of multiple antibodies, and various bispecific constructs, including some bispecifics in development by Sanofi, ABCL575 by Abcellera, NAV-240 by Navigator Medicines, and APG990 by AbbVie (previously by Apogee).

There are several other therapeutics in development for AD across several mechanisms, including regulatory T cell modulation, intracellular signaling and transcriptional regulation, cytokine pathways beyond IL-4/IL-13, longer-acting cytokine-targeted therapies and multi-specific approaches. Examples include rezpegaldesleukin, an IL-2/Treg-directed therapy being advanced by Nektar Therapeutics in Phase 3; KT-621, an oral STAT6 degrader being developed by Kymera Therapeutics; soquelitinib, an oral ITK inhibitor being developed by Corvus Pharmaceuticals; IL-18-targeting agents, including camoteskimab and EVO301; and multi-specifics targeting combinations of cytokines, T cell modulators and other targets.

We are also developing olevaprubart for the treatment of AA. There are several approved Janus kinase (JAK) inhibitors for the treatment of AA, including Eli Lilly's baricitinib, Pfizer's ritlecitinib and Sun Pharma's deuruxolitinib. There are several therapies in development for the treatment of AA, with biologics being particularly notable given the unmet need for therapies that may offer improved safety, tolerability and durability of response relative to currently available JAK inhibitors. Rezpegaldesleukin (NKTR-358), a pegylated IL-2 modulator, being developed by Nektar Therapeutics, is being developed for both AD and AA, and has announced plans to initiate a Phase 3 trial in AA in 2027. Other therapies in development include bempikibart, an IL-7Rα antibody being developed by Q32 Bio, which has announced plans to progress to registrational development. ATI-2138; LY4005130, an XCL1/XCL2-neutralizing monoclonal antibody being developed by Eli Lilly in Phase 2; FB102, an anti-CD122 mAb originally developed by Forte Biosciences and now owned by argenx, and ALM223, an IL2 mutant fusion protein being developed by Almirall in Phase 2.

The enrollment and retention of patients in clinical trials for olevaprubart may be disrupted or delayed as a result of clinicians' and patients' perceptions as to the potential advantages and safety considerations of olevaprubart in relation to commercially available therapies and other programs in development, including approved products as well as any other new products that may be approved in the future.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects, have more convenient dosing regimens, or are less costly than any product candidates that we may develop, which could render any future product candidates obsolete and noncompetitive.

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

Our potential future competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and commercializing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, or as a result of the development of drug products that have more convenient dosing regimens. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development of olevaprubart and any future product candidates.

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

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

Coverage and reimbursement may be limited or unavailable in certain market segments for olevaprubart or any future product candidates, which could make it difficult for us to sell olevaprubart or any future product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may also be particularly difficult because of the higher prices often associated with such drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use olevaprubart or any future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services ("CMS") revises the reimbursement systems used to reimburse healthcare providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use olevaprubart or any future product candidates. In addition, there has been increasing legislative and enforcement interest in the United States with respect

to specialty drug pricing practices. 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. In addition, HHS has been empowered to negotiate the price of certain single-source 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 twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In the EU, some EU Member States may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, medicinal products may be subject to Health Technology Assessments ("HTA") at the EU and national levels. This HTA is a multidisciplinary process that summarizes 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 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. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

The marketability of olevaprubart or any future product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Clinical trial subject injury and product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of olevaprubart or any future product candidates that we may develop.

The use of olevaprubart or any future product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of clinical trial subject injury and product liability claims. Product liability claims might be brought against us by consumers, healthcare professionals, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize olevaprubart or any future product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for olevaprubart or any future product candidates, if approved for commercial sale; and
- loss of revenue.

Risks Related to Government Regulation

The regulatory approval process of the FDA and comparable foreign regulatory authorities is lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for olevaprubart or any future product candidates, and any such regulatory approval may be for a more narrow indication than we seek.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and comparable foreign regulatory authorities in and outside the United States. We are not permitted to market any biological drug product in the United States or outside the United States until we receive approval of a BLA from the FDA or similar approvals from comparable foreign regulatory authorities. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA and similar applications must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA and similar applications must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product.

Olevaprubart or any future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory authorities that olevaprubart or any future product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of olevaprubart or any future product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market olevaprubart or any future product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve olevaprubart or any future product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Even if olevaprubart or any future product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval.

The FDA may also require a panel of experts, referred to as an "Advisory Committee," to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Similar requirements may apply outside the United States.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Accordingly, the regulatory approval pathway for olevaprubart or any future product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows 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 by all EU Member States concerned, 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 via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresees a three-year transition period. On January 31, 2025, all ongoing trials became subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, the EU pharmaceutical legislation is currently the subject of proposals for a complete review, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. 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 enter into force in late 2026 and 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 biosimilar market entry, could increase competition and adversely affect the commercial prospects of any product candidates we are able to commercialize in the EU.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS or comparable foreign strategies. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations and prospects.

We have conducted and intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have conducted certain of our clinical trials globally including in Canada and Australia and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of data from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the 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, (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 foreign clinical trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the clinical trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be 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 could result in the need for

additional trials, which could be costly and time-consuming, and which may result in olevaprubart or any future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practices and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving these designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various designations by regulatory authorities, such as Fast Track Designation or PRIority MEdicine ("PRIME") Designation from regulatory authorities, for olevaprubart or any future product candidates that we develop. If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for Fast Track Designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. If granted, fast track designation makes a drug eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Products with Fast Track designation may also be eligible for accelerated approval and priority review, if the relevant criteria are met.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the European Medicines Agency's ("EMA") support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical program to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, the applicable regulatory authority may determine not to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EMA, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

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

Obtaining and maintaining regulatory approval of olevaprubart or any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by

regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, pricing or reimbursement approval may be required before a product can be commercially launched or meaningfully accessed in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

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

Any regulatory approvals that we receive for olevaprubart or any future product candidates will require surveillance to monitor the safety and efficacy of such product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") in order to approve olevaprubart or any future product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves olevaprubart or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for olevaprubart or any future product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA or comparable foreign regulatory authorities could require us to conduct another study to obtain additional safety or biomarker information.

Further, we will be required to comply with FDA and comparable foreign regulatory authorities' promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Although 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, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with olevaprubart or any future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS or similar foreign program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of olevaprubart or any future product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, untitled letters, warning letters or holds on clinical trials;
- the FDA or comparable foreign regulatory authority may require revisions to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- the FDA or comparable foreign regulatory authority may require the conduct of an additional post-market clinical trial or trials to assess the safety of the product;
- refusal by the FDA or comparable foreign regulatory authority to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of olevaprubart or any future product candidates; and

- injunctions or the imposition of civil or criminal penalties.

FDA and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of olevaprubart or any future product candidates. For example, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Certain policies of any administration may impact our business and industry. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and our third-party manufacturers or suppliers and current or potential future collaborators may use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. The operations of our third-party manufacturers and suppliers also produce, and our operations may produce, hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our relationships with customers, physicians, other healthcare professionals and third-party payors are subject, directly or indirectly, to federal, state, local and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.

Healthcare professionals and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of olevaprubart or any future product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed 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 and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term

"remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, including any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal civil False Claims Act ("FCA") and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Private individuals, commonly known as "whistleblowers," can bring federal civil FCA qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement;
- the Health Insurance Portability and Accountability Act ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements 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 ("HITECH"), and their respective implementing regulations, which impose requirements on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that perform services for them that involve creating, receiving, maintaining or transmitting protected health information ("PHI") and their subcontractors that use, disclose, access, or otherwise process PHI, relating to the privacy, security and transmission of individually identifiable health information. Penalties for HIPAA violations can be significant. They vary greatly depending on the nature of violation, and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state, local and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also 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 physicians 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 "Sunshine Acts" may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g., annual) basis.

Also, we may be subject to the following: state and foreign laws that require certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; 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, or that apply regardless of payor; 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 federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures; state and foreign laws that require the reporting of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and significant penalties. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of olevaprubart or any future product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Olevaprubart will be regulated as a biologic, and therefore it may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA.

We believe that any of the product candidates we develop that is approved in the United States under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product.

For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

The approval of a biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products. The changes introduced by the Pharma Package may further facilitate earlier market entry of biosimilar products following the expiry of applicable regulatory and intellectual property protections.

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

The use of olevaprubart for the treatment of moderate-to-severe AD, AA or other potential indications or any of our future product candidates may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Factors that will influence whether olevaprubart or any future product candidates are accepted in the market include:

- the clinical indications for which olevaprubart or any future product candidates are approved;
- physicians, hospitals and patients considering olevaprubart or any future product candidates as a safe and effective treatment;

- the potential and perceived advantages of olevaprubart or any future product candidates over alternative treatments;
- the incidence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of olevaprubart or any future product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience, frequency and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If olevaprubart or any future product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

The advancement of healthcare reform may negatively impact our ability to profitably sell olevaprubart or any future product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to profitably sell olevaprubart or any future product candidates, if approved. In particular, in 2010 the Affordable Care Act ("ACA") was enacted which, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including olevaprubart, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

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

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, aggregate reductions to Medicare payments to providers went into effect beginning on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect through 2032, unless additional congressional action is taken. In addition, Congress is considering health reform measures as part of other health reform initiatives.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. For example, the current administration announced agreements with certain 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, 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. These actions and proposals may, for example, include directives: (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 improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's recent Strategy Report, 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* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and Canada.

In the EU, similar developments may affect our ability to profitably commercialize olevaprubart or any future product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or Member State level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicinal products, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States have resulted in restrictions on the pricing and reimbursement of medicinal products by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of olevaprubart or any future product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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 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 is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The 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. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions. Any adverse or delayed HTA outcomes, or divergent national reimbursement decisions, could negatively affect our ability to obtain or maintain favorable pricing and reimbursement status for any product candidates, if approved. 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.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

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

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security, including in connection with clinical trials in the United States and abroad.

In the United States, federal state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, health information privacy laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) which may be 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.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to whom the CCPA applies to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state consumer privacy laws exempt some data processed in the context of clinical trials, but these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work (including our collaborators). Similar laws have passed and are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Regulators are also increasingly scrutinizing certain personal data transfers and have proposed and enacted certain data localization or transfer requirements. 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 restriction 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 operate in the clinical trial space and impacts our ability to engage in transactions or agreements with certain third parties.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), Australia's Privacy Act, and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under the GDPR, in the event of non-compliance, companies face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; and private litigation related to processing of personal data brought by classes of data subjects and consumer protection organizations authorized at law to represent their interests.

In Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), apply to our operations. Australia's Privacy Act also applies to our operations. We also conduct studies in Asia and are or may become subject to new and emerging data privacy regimes in Asia, including China's PIPL and Korea's Personal Information Protection Act ("PIPA"). For example, China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator. India's new privacy legislation, the Digital Personal Data Protection Act ("DPDP"), may also apply to our operations.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States and other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

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

In addition to data privacy and security laws, we are and may become contractually subject to industry standards adopted by industry groups. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Moreover, clinical trial subjects about whom we or the third parties with whom we work obtain information may contractually limit our ability to use and disclose such information.

We publish privacy policies, marketing materials and other statements, concerning data privacy, and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our personnel use artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI and automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we, or the third parties with whom we work (including our collaborators and third-party providers) fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

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.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

Our activities may subject us to various laws relating to foreign and U.S. investments and other transactions, and our failure to comply with these laws could subject us to substantial fines and other penalties, which could adversely affect our business.

With respect to foreign investments, transactions in which we participate may be subject to U.S. laws that regulate foreign investments in and other transactions with U.S. businesses. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the implementing regulations thereof administered by the Committee on Foreign Investment in the United States ("CFIUS") and codified at 31 C.F.R. Part 800 (the "CFIUS Regulations").

The CFIUS Regulations authorize CFIUS to review certain foreign investments in and acquisitions of U.S. businesses, and to prohibit, modify, or unwind transactions subject to CFIUS jurisdiction in the event the transaction is determined to raise national security concerns.

With respect to U.S. investment transactions, certain of our activities may be subject to the Outbound Investment Security Program ("OISP") implemented to effectuate Executive Order 14105, administered by the Department of the Treasury, and codified at 31 C.F.R. Part 850 (the "OISP Regulations").

The OISP Regulations prohibit or require notification to the Department of the Treasury of certain transactions involving U.S. persons and persons with a qualifying nexus to China (including Hong Kong and Macau) that are engaged in specified activities in the semiconductors and microelectronics, quantum information technology, and AI sectors.

Application of these laws may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting mergers and acquisitions, investments, or collaborations we may pursue; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines, government investigations, business disruption, reputation harm, and other penalties if we do not.

Risks Related to Our Intellectual Property

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

We rely, and will continue to rely, upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to olevaprubart. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to olevaprubart and any future product candidates we may develop. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to olevaprubart or any future product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Composition of matter patents for biological and 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. Although our licensing partner Hutchmed received a composition of matter patent in the U.S. and Taiwan for olevaprubart, we cannot be certain that the claims in Hutchmed's pending patent applications directed to composition of matter of olevaprubart will be considered patentable by patent offices in other 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 for an indication that is outside the scope of the patented method.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover olevaprubart and any future product candidates we may develop in the United States or in other foreign countries, in whole or in part. Alternately, the existing patents that we own or in-license and any future patents we obtain may not be sufficiently broad to prevent others from developing competing products and technologies. It is possible that not all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Even if patents do successfully issue and even if such patents cover olevaprubart and any future product candidates we may develop, third parties may challenge their validity, ownership, enforceability or scope thereof, which may result in such patents being narrowed,

invalidated, or held unenforceable or circumvented. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of olevaprubart or any future product candidates. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing olevaprubart or any future product candidates, if approved, or practicing our own patented technology. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Further, if we encounter delays in regulatory approvals, the period of time during which we could market olevaprubart or any future product candidate under patent protection could be reduced. If any of our patents expire or are challenged, invalidated, circumvented or otherwise limited by third parties prior to the commercialization of olevaprubart or any future product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting olevaprubart or any future product candidates, competitors and other third parties could market products and use processes that are substantially similar, or superior, to ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to olevaprubart or any future product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of olevaprubart or any future product candidates, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could harm our business.

We are a party to the Hutchmed Agreement which is important to our business, and we may enter into additional license agreements in the future. Our Hutchmed Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payments, royalties and other obligations on us. See Note 10 - *Commitments and Contingencies* to our condensed consolidated financial statements included elsewhere in this Quarterly Report. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, or, in some cases, under other circumstances, the licensor may have the right to terminate the license, in which event we would not be able to market product candidate(s) covered by the license.

The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal, scientific and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. The standards that the United States Patent and Trademark Office ("USPTO") and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect olevaprubart or any future product candidates, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords, is limited. Without patent protection for olevaprubart or any future product candidates, we may be open to competition from biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of olevaprubart or any future product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell olevaprubart and any future product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. 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 or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, olevaprubart or any future product candidates. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing olevaprubart or any future product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that olevaprubart or any future product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may be subject to third-party claims including patent infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. There may be third-party patents or patent applications with claims to compositions, formulations, or methods of treatment, prevention use, or manufacture of olevaprubart or any future product candidates or technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that olevaprubart or any future product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to progress the clinical development of or commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

We also may be subject to third party claims arising from prior employment agreements or consulting agreements entered into by our officers, employees, independent contractors and consultants. Claims may include breach of nondisclosure, nonuse, noncompetition and non-solicitation provisions, intellectual property assignment and ownership, and misuse or misappropriation of intellectual property, trade secrets and other confidential information, among others. If a court of competent jurisdiction finds that we breached the provisions of third-party consulting agreements, we may be prohibited from using certain intellectual property, trade secrets and confidential information, effectively blocking our ability to seek patent protection for our inventions and halting the progress of our clinical development and commercialization efforts.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's intellectual property rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated, as parties making claims against us may obtain injunctive or other equitable relief. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from

commercializing olevaprubart or any future product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify olevaprubart or any future product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products, services and technology. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize olevaprubart or any future product candidates.

Competitors may infringe our patents or other intellectual property. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering olevaprubart or any future product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description, or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on olevaprubart or any future product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our shares could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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, manufacture and market olevaprubart or any future product candidates.

It is possible that our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are not complete or thorough. It is also possible that we have not identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of olevaprubart or any future product candidates in any jurisdiction. Patent applications in the United States, the EU and elsewhere are 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. Therefore, patent applications covering olevaprubart or any future product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover olevaprubart or any future product candidates or the use of such product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market olevaprubart or any future product candidates. We may incorrectly determine that olevaprubart or any future 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, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and

market olevaprubart or any future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market olevaprubart or any future product candidates, if approved.

If we fail to identify or correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing olevaprubart or any future product candidates. We might, if possible, also be forced to redesign olevaprubart or any future product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect olevaprubart or any future product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property, particularly our patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act ("AIA") which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

The U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Further, on June 1, 2023, the European Patent Package ("EU Patent Package") regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC"), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies provided by the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. We will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits, if any, of the new unified court.

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

The USPTO, European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction, or loss of entitlement or unenforceability against third parties. Non-compliance events that could result in abandonment or lapse or loss of entitlement or unenforceability of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering olevaprubart or any future product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully progress clinical development of or commercialize olevaprubart or any future product candidates in any indication for which they may be approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering olevaprubart or any future product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. 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. In-licensing patents covering olevaprubart or any future product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize olevaprubart or any future product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but where enforcement is not as strong as that in the United States or the EU. These products may compete with olevaprubart or any future product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability with respect to written description and experimental data in support of a claimed drug or medical use. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to

market olevaprubart or any future product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize olevaprubart or any future product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions including EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for olevaprubart or any future product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of olevaprubart or any future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, olevaprubart and any future product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Our proprietary rights may not adequately protect olevaprubart or any future product candidates, and 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. The following examples are illustrative:

- others may be able to make products that are the same as or similar to olevaprubart or any of our future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our or our licensors' pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- we may not exclusively license our patents and, therefore, may not have a competitive advantage if such patents are licensed to others;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider trade secrets and confidential know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, collaborators and suppliers. Because we rely on third parties to manufacture olevaprubart, may continue to do so in the future and expect to collaborate with third parties on the development of olevaprubart or any future product candidates we develop, we may, at times, share trade secrets and confidential know-how with them. We also conduct joint research and development programs that may require us to share trade secrets and confidential know-how under the terms of our research and development partnerships or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential know-how increases the risk that such trade secrets and confidential know-how become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our confidential know-how and trade secrets, a competitor's discovery of our trade secrets or confidential know-how or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. Further, we may need to share our trade secrets and confidential know-how with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets or confidential know-how, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets and confidential know-how, our competitors may discover them, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets or confidential know-how would impair our competitive position and have an adverse impact on our business.

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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of

other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and 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 secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, olevaprubart or any future product candidates may require the use of additional proprietary rights held by third parties. Olevaprubart or any future product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

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 an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect trade secrets, confidential know-how, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our confidential know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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

We do and will continue to employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the know-how or confidential information of their former employer or other third parties, we may be subject to claims that we or our employees, consultants, collaborators or independent contractors have inadvertently or otherwise used or disclosed know-how or confidential information of their former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents.

Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we do fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could result in customers seeking other sources for the technology, or in ceasing from doing business with us. Any such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to progress our clinical development programs or commercialize olevaprubart or any future product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to our Industry and Business

We will need to expand our organization, and we may experience challenges in managing this growth as we build our capabilities, which could disrupt our operations.

As of September 30, 2026, we had 22 full-time employees. We will need to expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of olevaprubart or any future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize olevaprubart or any future product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our executive officers, as well as the other members of our management, scientific and clinical teams. Any of our executive officers may terminate their employment with us at any time. In addition our executive officers are entitled to receive certain severance benefits in connection with their voluntary resignation of employment for good reason, as defined in their applicable employment or severance agreements.

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

If our information technology systems or those third parties with whom we work or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process confidential and sensitive data, including intellectual property, preclinical and clinical trial data, trade secrets, proprietary business information and personal information of employees, business partners and service providers (collectively, "sensitive information") necessary to conduct our business in our and the third parties' with whom we work data centers and networks. The secure processing, maintenance and transmission of this sensitive information is critical to our operations. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work (including our current and future CROs). Such threats are prevalent, continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel, sophisticated nation states and nation-state supported actors, including via advanced persistent threat intrusions.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. 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 cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We, and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social engineering attacks (including through deep fakes, which are increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced threat intrusions), ransomware attacks, supply-chain attacks, denial-of-service attacks, credential stuffing attacks, credential harvesting, server malfunction, personnel misconduct or error, software bugs, software and hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, natural disasters (such as earthquakes, fires, and floods), terrorism, war and telecommunication and electrical failures or other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent 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 harm and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment or those of third parties with whom we work to gain access to other parts of the relevant environments, 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. Remote work poses risks to our information technology systems and data, as our personnel utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

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

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, email, clinical trials and other functions. Our ability to monitor these third parties' information security practices is limited, and the third parties with whom we work may not have adequate information security measures in place. If these parties experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their data 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' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

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

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

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures designed to protect our information technology systems and sensitive information. 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 to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions are costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or the third parties with whom we work) experience a security incident or are perceived to have experienced a security incident, we could face adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations, monetary fund diversions, diversion of management attention, negative publicity; reputational harm; financial loss, interruptions in our operations (including availability of data), disruptions to our operations; and a loss of confidence in us and our ability to conduct clinical trials. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our sensitive information could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of sensitive information, we could incur liability, and the further development of olevaprubart or any future product candidates could be delayed. Further, our insurance coverage may not be sufficient to cover the financial, legal, arise from our privacy and security practices, including any compromise of our data or information technology systems. We also cannot be sure that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. 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 AI technologies.

Our business is subject to risks arising from pandemic and epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of olevaprubart or any future product candidates for use in our clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and

recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial due to disease progression in participants, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA or other comparable foreign regulatory authorities, which could result in delays in meetings related to our ongoing or planned clinical trials, as well have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

We or the third parties upon whom we depend may be adversely affected by a fire and earthquake or other man-made or natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our principal executive offices are located in San Diego, California and are vulnerable to fires and earthquakes. Any unplanned event, such as a flood, fire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications 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 man-made disasters on our third-party CMOs and CROs, 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 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 we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot provide assurance that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, 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 insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, workers' compensation, clinical trials/products liability, cybersecurity liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have key person life insurance policies on any such individuals. Therefore, if any of our key personnel die or become disabled, the loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

Our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, EU and comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy and security laws, and fraud and abuse and other healthcare laws and regulations; or (iv) other laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

Our ability to use net operating loss carryforwards and other tax attributes may be limited, including as a result of the Merger.

As of December 31, 2025, we had U.S. federal net operating loss ("NOL") carryforwards and state NOL carryforwards of $267.0 million and $81.5 million, respectively. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with the Merger or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, the Inflation Reduction Act and OBBBA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in

corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges and could increase our future U.S. tax expense.

Risks Related to Ownership of Our Common Stock

The market price of our common stock is expected to be volatile.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for olevaprubart and any future product candidates, and delays or failures to obtain such approvals;
- failure of olevaprubart or any of our future product candidates, if approved, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to olevaprubart or our future product candidates;
- any inability to obtain adequate supply of olevaprubart or our future product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

We will incur significant legal, accounting and other expenses that Legacy Inmagene did not incur as a private company, including costs associated with public company reporting requirements.

We will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, our management team includes executive officers, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers, which may adversely affect investor confidence in us and could cause our business or stock price to suffer.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit the ability of our stockholders to obtain a favorable judicial forum for disputes with the Company.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or our amended and restated certificate of incorporation or our amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, which is referred to as the "Delaware Forum Provision." The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which is referred to as the "Federal Forum Provision." In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses in our amended and restated bylaws may limit the ability of our stockholders to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce the Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

An active trading market for our common stock may not be sustained and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for the Legacy Inmagene shares. An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Substantial future sales of shares of our common stock could adversely affect the market price of such shares.

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, or there is the perception that these sales could occur, this could adversely affect the market price of such shares and could materially impair our ability to raise capital through equity offerings in the future. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including the Warrant Shares or shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

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

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

We identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the preparation of Legacy Inmagene's financial statements for the years ended December 31, 2024 and 2023, we identified a material weakness in our internal control over financial reporting, which had not been remediated as of September 30, 2026. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design and maintain effective controls related to the period-end financial reporting process to ensure adequate segregation of duties, including controls related to account reconciliations and journal entries. Specifically, certain personnel have incompatible duties including the ability to (i) create and post manual journal entries without an independent review and (ii) prepare and review account reconciliations. The material weakness did not result in a misstatement to our condensed consolidated financial statements.

However, this material weakness could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

To remediate the material weakness, we plan to design and implement control activities in response to the risks posed as a result of the lack of segregation of duties related to journal entries and account reconciliations, including general controls over information systems. The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct this material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate the existing material weakness or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes Oxley Act") in a timely manner, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and the market price of our common stock could be negatively affected. As a result, we could also become subject to investigations by Nasdaq, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Legacy Inmagene was never required to test its internal controls within a specified period. As a public company, we will need to incur substantial professional fees and internal costs to expand our accounting and finance functions and expend significant management efforts.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Because of these inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development program and the diseases olevaprubart is being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harms to our business.

General Risk Factors

Unstable market and economic conditions, including any adverse macroeconomic conditions or geopolitical events, may have serious adverse consequences on our business, financial condition and stock price.

The 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, supply chain constraints, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of public health crises, geopolitical conflicts (including military conflicts, threatened hostilities, and conflicts or heightened tension among alliance countries), terrorism or other geopolitical events. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Sanctions imposed by the United States and other countries in response to military conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. 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 credit and financial markets and confidence in economic conditions will not occur. Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

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

In August 2026, we issued 1,038,482 shares of common stock (the "Exercised Warrant Shares") upon exercise of 1,038,516 pre-funded warrants for the purchase of shares of common stock of the Company at an exercise price of $0.001 per share including 846,172 Exercised Warrant Shares that were exercised for cash and 192,344 pre-funded warrants that were net exercised for an aggregate of 192,310 Exercised Warrant Shares for no additional cash consideration. The pre-funded warrants were originally issued in a private placement and pursuant to a Securities Purchase Agreement in April 2026. The offer and sale of the Exercised Warrant Shares issued upon exercise of the pre-funded warrants was made in reliance on the exemption afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The holders of the pre-funded warrants represented that they are accredited investors, as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended, and that they were acquiring the securities for investment purposes only and not with a view to, or for resale in connection with any distribution of the securities in violation of U.S. federal securities laws.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Trading Arrangements

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

Item 6. Exhibits.

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated December 23, 2024, by and among the Registrant, Insight Merger Sub I, Insight Merger Sub II, and Inmagene Biopharmaceuticals (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on December 23, 2024).
3.1	Fifth 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 (File No. 001-40287) filed with the SEC on March 30, 2021).
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Registrant, dated July 25, 2025 (Stock Split Amendment) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Registrant, dated July 25, 2025 (Name Change Amendment) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
3.4	Amended and Restated Bylaws of the Registrant dated March 20, 2021 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on March 30, 2021).
4.1	Registration Rights Agreement by and among the Registrant and the parties thereto, dated July 25, 2025 (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
4.2	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on April 13, 2026).
4.3	Registration Rights Agreement dated April 14, 2026, by and between the Registrant and the Investors (incorporated by reference to Exhibit 4.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-40287) filed with the SEC on May 7, 2026).
10.1	Offer of Employment between the Company and Yanina Grant-Huerta (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 23, 2026).
10.2*†+	Novation and Termination Agreement, dated July 20, 2026, by and among the Registrant, HUTCHMED Limited (Hutchison MediPharma Limited), Inmagene Biopharmaceuticals (Hangzhou) Co., Ltd., Insight Merger Sub II, and Miragene Inc.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† Certain portions of this exhibit (indicated by asterisks) have been redacted because they are not material and are the type of information that the Company treats as private or confidential.

+ The annexes, schedules, and certain exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K.

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.

ImageneBio, Inc.

Date: November 9, 2026

By: /s/ Kristin Yarema
Kristin Yarema, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2026

By: /s/ Yanina Grant-Huerta
Yanina Grant-Huerta
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.2

CONFIDENTIAL
Execution Version

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) IS THE TYPE THAT IMAGENEBIO TREATS AS PRIVATE AND CONFIDENTIAL.

NOVATION AND TERMINATION AGREEMENT

This NOVATION AND TERMINATION AGREEMENT (this "Agreement") is made as of July 20, 2026, (the "Effective Date"), by and among 和记黄埔医药（上海）有限公司 HUTCHMED Limited (formerly Hutchison MediPharma Limited) ("HUTCHMED" or "Hutchison"), ImageneBio, Inc. ("ImageneBio"), Inmagene Biopharmaceuticals (Hangzhou) Co., Ltd. ("Inmagene CN"), Insight Merger Sub II ("Merger Sub" and with ImageneBio and Inmagene CN, the "ImageneBio Entities") and Miragene Inc ("Miragene").

WITNESSETH

WHEREAS, HUTCHMED and Inmagene Biopharmaceuticals are parties to that certain Collaboration, Option and License Agreement, dated as of January 5, 2021, as amended by the First Amendment to the Collaboration, Option and License Agreement dated April 21, 2023, the Second Amendment to the Collaboration, Option and License Agreement dated December 15, 2023, and that certain Supplementary Agreement to the Collaboration, Option, and License Agreement, dated as of February 8, 2022 (collectively, the "Collaboration Agreement"), copies of which are attached hereto as Exhibit A;

WHEREAS, HUTCHMED, Inmagene Biopharmaceuticals, and Inmagene CN are parties to that certain Tripartite Agreement, dated as of May 26, 2022 (the "Supplemental Agreement"), a copy of which is attached hereto as Exhibit B, pursuant to which Inmagene Biopharmaceuticals assigned certain rights and obligations with respect to research and development activities under the Collaboration Agreement to Inmagene CN;

WHEREAS, Inmagene Biopharmaceuticals exercised its option under the Collaboration Agreement on October 16, 2023 to obtain an exclusive license from HUTCHMED for the (a) BTK (Bruton tyrosine kinase) inhibitor HMPL-727 (also known as IMG-004) (as defined therein, the "**BTK Asset**") and (b) humanized OX40 (CD134) antagonistic monoclonal antibody, in each case, as described in the Collaboration Agreement;

WHEREAS, Inmagene Biopharmaceuticals sublicensed its rights under the Collaboration Agreement with respect to the BTK Asset to Miragene, a wholly owned subsidiary of Miragene Co, pursuant to the Sublicense Agreement, by and between Inmagene Biopharmaceuticals and Miragene Inc, dated as of July 24, 2025, (the "Sublicense Agreement"), a copy of which is attached hereto as Exhibit C;

WHEREAS, in connection with that certain merger transaction, Inmagene Biopharmaceuticals merged with Insight Merger Sub II, with Insight Merger Sub II surviving as a wholly owned subsidiary of ImageneBio and the contracting party under the Collaboration Agreement (with HUTCHMED) and Sublicense Agreement (with Miragene Inc);

WHEREAS, HUTCHMED and Miragene desire to enter into a direct license for HUTCHMED's rights to the BTK Asset;

WHEREAS, to effectuate such direct license, ImageneBio Entities now desire to terminate the licenses granted to the ImageneBio Entities under the Collaboration Agreement solely with respect to the BTK Asset and novate their rights and obligations under the Sublicense Agreement to HUTCHMED;

WHEREAS, after the termination of the Collaboration Agreement solely with respect to the BTK Asset, HUTCHMED will assume, via novation, the Sublicense Agreement such that HUTCHMED directly grants the same rights in the BTK Asset to Miragene; and

WHEREAS, the parties are entering into this Agreement to novate the Sublicense Agreement and to terminate the Collaboration Agreement solely with respect to the BTK Asset, in each case, on the terms and conditions stated herein.

NOW, THEREFORE, intending to be legally bound hereby, the parties hereto agree as follows:

1. **Definitions**. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Sublicense Agreement.

2. **Novation.** As of the Effective Date, HUTCHMED shall, by way of novation, assume all rights of the ImageneBio Entities under the Sublicense Agreement (the "Assumed Rights"), and be bound by and perform all obligations, and assume responsibility for all liabilities, of the ImageneBio Entities under the Sublicense Agreement arising on or after the Effective Date, other than Excluded Liabilities ("Assumed Liabilities"). As used herein, "Excluded Liabilities" means any liabilities of the ImageneBio Entities or any of their Affiliates to any Person and claims from any Person to the extent relating to or arising out of circumstances existing on or prior to the Effective Date. Miragene hereby releases and discharges the ImageneBio Entities from any and all Assumed Liabilities and agrees that HUTCHMED shall assume and hereby does assume all the Assumed Rights under the Sublicense Agreement, and Miragene hereby expressly consents to the substitution, by way of novation, of HUTCHMED in place of the ImageneBio Entities with respect to all of the rights, title, interests, obligations, duties, covenants and liabilities of the ImageneBio Entities under the Sublicense Agreement other than the Excluded Liabilities. The ImageneBio Entities, HUTCHMED, and Miragene each agree that, as of and after the Effective Date, the ImageneBio Entities, shall cease to be subject to, or liable under, the Sublicense Agreement for any Assumed Liabilities. For clarity, from and after the Effective Date, HUTCHMED shall be deemed, with respect to the BTK Asset, to have directly granted to Miragene the same rights of HUTCHMED sublicensed to Miragene under the Sublicense Agreement, as novated and amended hereby, as if HUTCHMED and Miragene were the original parties to such Sublicense Agreement. HUTCHMED acknowledges and agrees that this Agreement is intended to preserve in full the rights of HUTCHMED granted to Miragene under the Sublicense Agreement with respect to BTK Asset. Additionally, the ImageneBio Entities represent and warrant, as of immediately prior to the Effective Date, that no intellectual property or other rights owned by the ImageneBio Entities are licensed under the Sublicense Agreement, such that the only rights granted under the Sublicense Agreement are owned by HUTCHMED. Except as expressly set forth in this Agreement, nothing in this Agreement or the novation contemplated hereby is intended to reduce, limit, impair or otherwise adversely affect Miragene's rights under the Sublicense Agreement with respect to the BTK Asset. Without limiting the foregoing, the termination of the Collaboration Agreement solely with respect to the BTK Asset shall not affect, diminish or impair Miragene's rights under the Sublicense Agreement with respect to the BTK Asset, all of which shall remain in full force and effect directly as between HUTCHMED and Miragene.

3. **Amendment to the Sublicense Agreement**.

   a. **As of the Effective Date, Section 10.1.9 (Reversion Financials to Miragene) of the Sublicense Agreement shall be deleted in its entirety and replaced with the following:**

   "10.1.9. **Reversion Financials to Miragene**. In the event that (a) this Agreement terminates in its entirety due to Miragene's termination for HUTCHMED's uncured material breach under Section 9.2 or (b) this Agreement terminates with respect to the Licensed Compound due to HUTCHMED's termination under Section 9.6 and, in each case (a) and (b), Miragene has completed at least [***] for a Terminated Product subject to such termination, HUTCHMED will pay a [***] royalty to Miragene on Net Sales (such definition as revised *mutatis mutandis*) of such Terminated Product(s) in the Territory for any indication for which [***] (the "Reversion Royalty"). The Reversion Royalty shall be payable on a country-by-country basis and Terminated Product-by-Terminated Product basis for the period beginning on the First Commercial Sale of such Terminated Product in such country and ending upon on the earlier of: (x), the longer of (i) [***] and (ii) the [***], and (y) [***]. The Reversion Royalty will be subject to reductions as described in Section 6.2.3, *mutatis mutandis*. Miragene's recordkeeping obligations and HUTCHMED's right to audit with respect to Miragene's development costs will be as set forth in Section 6.11,

mutatis mutandis; provided that HUTCHMED's obligation to pay the Reversion Royalties under this Agreement post-termination are subject to [***]."

b. With respect to the Sublicense Agreement, effective as of the Effective Date, the contact information of the ImageneBio Entities as set forth in Section 13.8 (Notices) shall be deleted in its entirety and replaced with the following language:
"HUTCHMED Limited
和记黄埔医药（上海）有限公司
Building 4, 720 Cai Lun Road
ZJ Hi-Tech Park, Shanghai, PRC
Attention: [***]"

c. The parties acknowledge and agree that, as of the Effective Date, the following Sections of the Sublicense Agreement shall be deleted in their entireties: Section 2.1.4 (Hutchison License Agreement), Section 2.5 (Right of First Negotiation for Additional Compounds); Section 7.5; Section 8.8; Section 9.7 (Termination for Termination of the Hutchison License Agreement); Section 11.2.8 (Hutchison License Agreement); and Section 11.3 (ImageneBio Entities Covenants).

d. Notwithstanding any terms set forth in Section 13.1 (Assignment) of the Sublicense Agreement, the ImageneBio Entities shall have no further responsibility or liability for their obligations under the Sublicense Agreement except for the Excluded Liability as defined in Section 2 of this Agreement.

4. **Termination**. Notwithstanding any provision to the contrary set forth in the Collaboration Agreement, the ImageneBio Entities and HUTCHMED hereby terminate the Collaboration Agreement, effective as of the Effective Date, solely with respect to the BTK Asset and all Licensed Products (as defined in the Collaboration Agreement) containing the BTK Asset. On and after the Effective Date, the BTK Asset will be deemed a Terminated Product (as defined in the Collaboration Agreement) under the Collaboration Agreement.

5. **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the conflicts of law or choice of law provisions thereof.

6. **Successors and Assigns**. This Agreement shall be binding upon, be enforceable against, and inure to the benefit of the parties hereto and their respective successors and assigns.

7. **Further Assurances**. Following the Effective Date, each party will, to the extent reasonably requested by the other parties, execute and deliver such documents and instruments and take such other actions that such parties may reasonably request in order to consummate and make effective the transactions contemplated by this Agreement.

8. **Entire Agreement**. This Agreement is the sole and entire agreement of the parties to this Agreement regarding the subject matter contained herein and therein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, regarding such subject matter. Except as explicitly set forth in this Agreement, all duties, obligations and rights under the Collaboration Agreement remain unchanged.

9. **Amendment; Waiver**. No amendment to this Agreement is effective unless it is in writing and signed by each party to this Agreement. No waiver under this Agreement is effective unless it is in writing and signed by the party waiving its right. Any waiver authorized on one occasion is effective only in that instance and only for the purpose stated and does not operate as a waiver on any future occasion. None of the following is a waiver or estoppel of any right, remedy, power, privilege, or condition arising from this Agreement: (a) any failure or delay in exercising any right, remedy, power, or privilege or in enforcing any condition under this Agreement; or (b) any act, omission, or course of dealing between the parties.

10. **Severability**. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability does not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

11. **Headings; Counterparts**. The headings in this Agreement are for reference only and do not affect the interpretation of this Agreement. This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same instrument. Facsimiles and .PDFs of signatures may be taken as the actual signatures.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date above.

和记黄埔医药（上海）有限公司
HUTCHMED LIMITED

By:*/s/ May Wang*
Name: May Wang
Title: Executive Vice President,
Business Development & Strategic Alliances

By:*/s/ Johnny Cheng*
Name: Johnny Cheng
Title: Executive Director, Acting Chief Executive Officer and Chief Financial Officer

[*Signature Page to Novation and Termination Agreement*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date above.

IMAGENEBIO, INC.

By:*/s/ Kristin Yarema*
Name: Kristin Yarema
Title: CEO

INMAGENE BIOPHARMACEUTICALS (HANGZHOU) CO., LTD.

By:*/s/ Jonathan Wang*
Name: Jonathan Wang
Title: Director

INSIGHT MERGER SUB II

By:*/s/ Kristin Yarema*
Name: Kristin Yarema
Title: CEO

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date above.

MIRAGENE INC

By:*/s/ Jonathan Wang*
Name: Jonathan Wang
Title: Director

[*Signature Page to Novation and Termination Agreement*]

Exhibit 31.1

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

I, Kristin Yarema, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImageneBio, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 9, 2026

By: /s/ Kristin Yarema

Kristin Yarema, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Yanina Grant-Huerta, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImageneBio, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 9, 2026

By: /s/ Yanina Grant-Huerta
Yanina Grant-Huerta
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with this Quarterly Report on Form 10-Q for the period ending September 30, 2026 of ImageneBio, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of her knowledge:

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

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

Date: November 9, 2026 By: /s/ Kristin Yarema

Kristin Yarema, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2026 By: /s/ Yanina Grant-Huerta

Yanina Grant-Huerta
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)