
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, 2025

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
(State or other jurisdiction of
incorporation or organization)

12526 High Bluff Drive
Suite 345

San Diego, California
(Address of principal executive offices)

81-1697316
(I.R.S. Employer
Identification No.)

92130
(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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

As of November 3, 2025, the registrant had 11,181,672 shares of common stock, \$0.001 par value per share, outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (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, 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 IMG-007 and any future product candidates and to fund our continued operations;
- the initiation, timing and potential of planned or ongoing clinical trials for IMG-007, including the timing for data readouts;
- our progress, scope or timing of the development of IMG-007, including our plans to develop IMG-007 for additional immunological and inflammatory indications;
- expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of IMG-007 and anticipated milestones and timing therefor;
- our plans and expectations regarding our current or future collaborations;
- our ability to successfully commercialize IMG-007, if approved, the rate and degree of market acceptance of IMG-007 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 IMG-007;
- our planned use of cash and cash equivalents and the milestones we expect to fund with such proceeds;
- the accuracy of our estimates regarding our cash runway, expenses, future revenues 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 ongoing legal proceedings against us;
- our ability to recognize the benefits that may be derived from the Merger, including the commercial or market opportunity of IMG-007;
- developments and projections relating to our competitors, our industry or the market opportunities for IMG-007 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 you should not place undue reliance 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 that you should 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 IMG-007 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 IMG-007 for the treatment of AD 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;
- Our rights to develop and commercialize IMG-007 are subject, in part, to the terms and conditions of licenses granted to us by others;
- If we breach our current or future licenses or other intellectual property-related agreements for IMG-007 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;
- 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 are 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates;
- If we are unable to obtain and maintain patent protection for IMG-007 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;
- Legacy Inmagene identified a material weakness in its 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 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;
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan;
- We do not anticipate that we will pay any cash dividends in the foreseeable future;
- An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all;
- Future sales of shares by existing stockholders could cause our stock price to decline; and
- 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 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 consolidated financial statements and the related notes, as well as with other documents that we file with the United States Securities and Exchange Commission. 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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 103,162	\$ 12,118
Marketable securities	39,421	—
Prepaid expenses and other current assets (1)	4,949	350
Total current assets	147,532	12,468
Non-current assets:		
Operating lease right-of-use assets, net	884	547
Promissory note receivable from related party (Note 8)	7,510	—
Other non-current assets	4,952	1,019
Deferred offering costs	—	1,888
Total assets	\$ 160,878	\$ 15,922
Liabilities, Redeemable Convertible Preferred Shares and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,081	\$ 5,290
Accrued expenses and other current liabilities	6,902	3,460
Deferred revenue, current	—	650
Lease liabilities, current	2,161	309
Term loan	—	7,500
Total current liabilities	\$ 11,144	\$ 17,209
Non-current liabilities:		
Lease liabilities, non-current	1,284	239
CVR liability due to related party (Note 8)	7,510	—
Other non-current liabilities	1,108	—
Total liabilities	\$ 21,046	\$ 17,448
Commitments and contingencies (Note 12)		
Redeemable convertible preferred shares:		
Redeemable convertible preferred shares - \$0.00005 par value; no shares and 2,905,696 shares authorized as of September 30, 2025 and December 31, 2024, respectively; no shares and 2,163,434 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively; aggregate liquidation preference of \$0 and \$163,575 as of September 30, 2025 and December 31, 2024, respectively	—	159,039
Total redeemable convertible preferred shares	—	159,039
Stockholders' equity (deficit):		
Series A convertible preferred shares - \$0.00005 par value; no shares authorized as of September 30, 2025 and 994,869 shares authorized, issued and outstanding as of December 31, 2024	—	18,967
Preferred Stock - \$0.001 par value, 10,000,000 shares authorized as of September 30, 2025 and none authorized as of December 31, 2024, respectively; no shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	—	—
Voting Common stock - \$0.001 par value, 142,000,000 and 57,119,423 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 10,650,956 and 1,409,884 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	11	1
Non-Voting Common Stock - \$0.001 par value, 8,000,000 shares authorized as of September 30, 2025 and none authorized as of December 31, 2024, respectively; 530,716 shares and no shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	362,870	2,158
Accumulated deficit	(223,143)	(179,900)
Accumulated other comprehensive income (loss)	94	(1,791)
Total stockholders' equity (deficit)	139,832	(160,565)
Total liabilities, redeemable convertible preferred shares and stockholders' equity (deficit)	\$ 160,878	\$ 15,922

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

(1) Includes related party amount of \$0.8 million and zero at September 30, 2025 and December 31, 2024, respectively.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
License revenue	\$ —	\$ 3,500	\$ 800	\$ 3,500
Operating expenses:				
Research and development (1)	15,558	3,885	25,251	28,350
General and administrative	11,036	1,651	15,496	6,008
Total operating expenses	26,594	5,536	40,747	34,358
Loss from operations	(26,594)	(2,036)	(39,947)	(30,858)
Other income (expense):				
Interest income (expense), net	(96)	46	(409)	344
Other income (expense), net	1,837	(1,193)	1,841	(1,242)
Total other income (expense), net	1,741	(1,147)	1,432	(898)
Loss before income taxes	(24,853)	(3,183)	(38,515)	(31,756)
Income tax benefit	(74)	—	(74)	—
Net loss	\$ (24,779)	\$ (3,183)	\$ (38,441)	\$ (31,756)
Accretion of redeemable convertible preferred shares	(846)	(2,998)	(7,046)	(8,757)
Net loss attributable to common stockholders	<u>\$ (25,625)</u>	<u>\$ (6,181)</u>	<u>\$ (45,487)</u>	<u>\$ (40,513)</u>
Loss per share – basic and diluted:				
Common stock	<u>\$ (2.91)</u>	<u>\$ (2.58)</u>	<u>\$ (9.98)</u>	<u>\$ (19.14)</u>
Series A convertible preferred shares	<u>\$ (2.91)</u>	<u>\$ (2.58)</u>	<u>\$ (9.98)</u>	<u>\$ (19.14)</u>
Weighted average shares used to compute basic and diluted loss per share:				
Common stock	8,526,781	1,400,557	3,808,867	1,121,742
Series A convertible preferred shares	<u>270,345</u>	<u>994,869</u>	<u>750,707</u>	<u>994,869</u>
Comprehensive loss:				
Net loss	\$ (24,779)	\$ (3,183)	\$ (38,441)	\$ (31,756)
Other comprehensive loss:				
Unrealized gain on marketable securities	94	—	94	—
Foreign currency translation adjustment	(3)	2	(29)	(98)
Total comprehensive loss	<u>\$ (24,688)</u>	<u>\$ (3,181)</u>	<u>\$ (38,376)</u>	<u>\$ (31,854)</u>

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

- (1) Includes related party amount of \$0.4 million for the three and nine months ended September 30, 2025, respectively, and zero for the three and nine months ended September 30, 2024, respectively.

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 Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	2,163,434	\$ 159,039	994,869	\$ 18,967	1,409,884	\$ 1	\$ 2,158	\$ (179,900)	\$ (1,791)	\$ (160,565)
Issuance of common stock upon exercise of stock options	—	—	—	—	1,763	—	45	—	—	45
Stock based compensation	—	—	—	—	—	—	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)
Balance at March 31, 2025	2,163,434	\$ 162,090	994,869	\$ 18,967	1,411,647	\$ 1	\$ 16	\$ (186,784)	\$ (1,800)	\$ (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)
Balance at June 30, 2025	2,163,434	\$ 165,239	994,869	\$ 18,967	1,411,647	\$ 1	\$ 16	\$ (197,518)	\$ (1,817)	\$ (180,351)
Stock based compensation	—	—	—	—	—	—	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 Ikema stockholders for reverse recapitalization	—	—	—	—	4,071,958	4	83,030	—	—	83,034
Issuance of common stock in PIPE Financing, net of issuance costs of \$3.9 million	—	—	—	—	2,508,339	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)
Balance at September 30, 2025	—	\$ —	—	\$ —	11,181,672	\$ 11	\$ 362,870	\$ (223,143)	\$ 94	\$ 139,832
Balance at December 31, 2023	2,163,434	\$ 147,223	994,869	\$ 18,967	980,802	\$ 1	\$ —	\$ (143,323)	\$ (1,753)	\$ (126,108)
Common stock issuable pursuant to Hutchmed agreement	—	—	—	—	—	—	13,965	—	—	13,965
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	2,851	—	—	—	—	(2,851)	—	—	(2,851)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(38)	(38)
Net loss	—	—	—	—	—	—	—	(22,314)	—	(22,314)
Balance at March 31, 2024	2,163,434	\$ 150,074	994,869	\$ 18,967	980,802	\$ 1	\$ 11,114	\$ (165,637)	\$ (1,791)	\$ (137,346)
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	2,908	—	—	—	—	(2,908)	—	—	(2,908)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(62)	(62)
Net loss	—	—	—	—	—	—	\$ (6,259)	—	—	(6,259)
Balance at June 30, 2024	2,163,434	\$ 152,982	994,869	\$ 18,967	980,802	\$ 1	\$ 8,206	\$ (171,896)	\$ (1,853)	\$ (146,575)
Issuance of common stock pursuant to Hutchmed Agreement	—	—	—	—	429,082	—	—	—	—	—
Accretion of Redeemable Convertible Preferred Shares to redemption value	—	2,998	—	—	—	—	(2,998)	—	—	(2,998)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	2	2
Net loss	—	—	—	—	—	—	—	(3,183)	—	(3,183)
Balance at September 30, 2024	2,163,434	\$ 155,980	994,869	\$ 18,967	1,409,884	\$ 1	\$ 5,208	\$ (175,079)	\$ (1,851)	\$ (152,754)

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,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (38,441)	\$ (31,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6	1,119
Non-cash interest expense	489	—
Stock-based compensation expense	15,340	—
Accretion/amortization of premium/discount of available-for-sale securities	(33)	—
Amortization of right of use-assets	466	313
Gain on early extinguishment of lease liability	(149)	—
Loss on disposal of property and equipment	—	1,287
Non-cash research and development expenses for the common stock issuable pursuant to Hutchmed Agreement	—	13,965
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,574)	(233)
Other non-current assets	(1,277)	121
Accounts payable	(2,179)	(2,236)
Accrued expenses and other current liabilities	(9,945)	(731)
Deferred revenue	(650)	650
Operating lease liabilities	(694)	(343)
Other long-term liabilities	15	-
Net cash used in operating activities	\$ (40,626)	\$ (17,844)
Cash flows from investing activities:		
Cash divested in Non-OX40 divestiture	(5,215)	—
Proceeds from disposal of property and equipment	—	869
Purchases of marketable securities	(1,485)	—
Maturities and sales of marketable securities	2,250	10,151
Net cash provided by investing activities	\$ (4,450)	\$ 11,020
Cash flows from financing activities:		
Proceeds from term loan	15,000	—
Proceeds from exercise of stock options	45	—
Issuance costs in connection with reverse recapitalization	(5,338)	—
Cash acquired in connection with reverse recapitalization	54,631	—
Proceeds from common stock issued in PIPE Financing, net of issuance costs	71,130	—
Net cash provided by financing activities	135,468	—
Effects of exchange rates on cash and cash equivalents	652	117
Net increase (decrease) in cash and cash equivalents	\$ 91,044	\$ (6,707)
Cash and cash equivalents, beginning of year	\$ 12,118	\$ 15,321
Cash and cash equivalents, end of year	\$ 103,162	\$ 8,731
Supplemental disclosure of cash flow information:		
Cash paid for income taxes, net	\$ 14	\$ 1
Supplemental disclosure of non-cash investing and financing information:		
Accretion of redeemable convertible preferred shares	\$ 7,046	\$ 8,757
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	\$ —
Reverse recapitalization issuance costs in accrued expenses	\$ 3,500	\$ —
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

Description of Business

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 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 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 the 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 accounting principles generally accepted in the United States (“U.S. GAAP”). The Company determined that Legacy Inmagene was the accounting acquirer and Ikena was the accounting acquiree of the Merger in accordance 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 this Quarterly Report on Form 10-Q to the “Company,” “we,” “our,” or “us” 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 voting

and non-voting common stock for periods following the Merger and to Legacy Inmagene's ordinary shares for periods prior to the Merger.

PIPE Financing

Concurrently with the execution of the Merger Agreement, Ikena entered into subscription agreements with certain accredited investors (the "PIPE Investors"), pursuant to which, immediately following the closing of the Second Merger, the PIPE Investors subscribed for and purchased, and Ikena issued and sold, an aggregate of 2,508,339 shares of Ikena Common Stock in a private placement at a price of approximately \$29.90 per share for aggregate gross proceeds of approximately \$75.0 million (the "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 as of and for the period ended September 30, 2025.

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, IMG-007) (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 our 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, for the period ended September 30, 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 promissory note receivable was recognized, with any difference recorded in equity. No gain or loss was recognized in the condensed combined statement of operations 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 our condensed consolidated balance sheet.

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, 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 is six months (the "Initial Term"), which shall be automatically extended for an additional six months unless during the first three months of the Initial Term, the Company provides written notice to terminate the Transition Services Agreement. In addition, the Company may extend the Initial Term with respect to any or all of the Miragene Services for up to an additional 12 months upon 60 days' prior written notice prior to the end of the Initial Term.

Upon the closing of the Merger, the Company paid Miragene \$1.25 million as pre-payment for the Miragene Services to be provided during the Initial Term, of which \$0.4 million has been recognized as operating expense for the period ended September 30, 2025. Up to \$1.25 million may be payable if the Initial Term is automatically extended for the Miragene Services to be provided during such period.

The Transition Services Agreement may be 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, for total service fees of \$0.2 million.

Liquidity and Going Concern

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

The 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. Since inception, the Company has devoted substantially all of its resources to advancing the development of its portfolio of programs, organizing and staffing the Company, business planning, raising capital, and providing general and administrative support for these operations. Current and future programs will require significant research and development efforts, including preclinical and clinical trials, and regulatory approvals for commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure. 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 has not generated any revenue from product sales and has incurred significant operating losses and negative cash flows from operations since inception. The Company has incurred a net loss of \$ \$24.8 million and \$38.4 million for the three and nine months ended September 30, 2025, respectively. For the nine months ended September 30, 2025, the Company used net cash of \$40.6 million for its operating activities. As of September 30, 2025, the Company had cash, cash equivalents, and marketable securities of \$142.6 million.

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, government or private party grants, debt financings and license and collaboration agreements. Adequate funding may not be available to the Company on acceptable terms, or at all.

The Company believes its existing cash, cash equivalents and marketable securities of \$142.6 million as of September 30, 2025 are sufficient to support operations through at least the next 12 months from the date of issuance of these unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with U.S. GAAP and reflect the operations of the Company and its fully owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

These interim financial statements do not include all the information and footnotes required by U.S. GAAP for annual financial statements and should be read in conjunction with the Legacy Inmagene's audited financial statements for the year ended December 31, 2024, which are included in the Company's registration statement on Form S-1 (File No. 333-290108) (the "Registration Statement"), filed with the Securities and Exchange Commission (the "SEC") on September 8, 2025 and declared effective on September 15, 2025. In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of September 30, 2025, and its results of operations for the three and nine months ended September 30, 2025 and 2024, and cash flows for the nine months ended September 30, 2025 and 2024. The condensed consolidated balance sheet at December 31, 2024, was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements.

There have been no material changes to the Company's significant accounting policies as described in the Company's audited consolidated annual financial statements for the year ended December 31, 2024 that are included in the Registration Statement, except as noted below.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. 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, the fair value of common stock prior to the Merger and redeemable convertible preferred shares, the fair value of Promissory Note receivable and related CVR liability, and the amount and timing of revenue recognition. 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.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair

value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents, marketable securities, Promissory Note receivable and related CVR liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 4 - *Fair Value Measurements*). The carrying amounts of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities. The Company recognizes transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer.

Marketable Securities

The Company invests its excess cash balances in marketable securities and classifies its investments as available-for-sale based on facts and circumstances present at the time it purchased the securities. At each balance sheet date presented, the Company classified all of its investments in marketable securities as available-for-sale and as current assets as they represent the investment of funds available for current operations. The Company reports available-for-sale securities at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive loss, a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in the value of the marketable securities, the Company considers all available evidence to evaluate if an impairment loss exists, and if so, adjusts the investment to market value through a charge to its condensed consolidated statements of operations and comprehensive loss.

Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Accretion of discounts are recorded in interest income in the condensed consolidated statements of operations and comprehensive loss.

Net Loss Per Share

Prior to consummation of the Merger, Legacy Inmagene applied the two-class method to compute basic and diluted net loss per share attributable to common stockholders when it had issued shares that meet the definition of participating securities. The two-class method determined net loss per share for each class of common stock and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires loss available to common stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to share in the earnings as if all loss for the period had been distributed. Legacy Inmagene's redeemable convertible preferred shares were eligible to participate in any dividends declared by Legacy Inmagene and were therefore considered to be participating securities. The participating securities were not required to participate in the losses of Legacy Inmagene, and therefore during periods of loss there was no allocation required under the two-class method.

Prior to the consummation of the Merger, Legacy Inmagene had two classes of ordinary shares outstanding - ordinary shares and Series A convertible preferred shares. Basic net loss per share attributable to ordinary shareholders was computed by allocating the undistributed earnings for each period to each class on a proportionate basis. Net loss per share was computed by dividing the net loss attributable to each class of ordinary share by the weighted average number of ordinary shares of each class outstanding for the period. The two-class method was expected to yield the same basic loss per share for ordinary share and Series A convertible preferred shares as there were no differences in dividend rights between the two classes. Diluted net loss attributable to ordinary shareholders was computed by adjusting net loss per share attributable to ordinary shareholders based on the potential impact of dilutive securities. Diluted net loss per share attributable to ordinary shareholders was computed by dividing the diluted net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding for the period, including potential dilutive ordinary shares.

Legacy Inmagene's ordinary shares, Series A convertible preferred shares, and redeemable convertible preferred shares were exchanged for shares of the Company's common stock at the consummation of the Merger. Subsequent to the close of the Merger, the Company has two classes of common stock outstanding, voting common stock and non-voting common stock. The rights of the

holders of voting and non-voting common stock are identical, except with respect to voting. Each share of non-voting common stock is convertible into one share of voting common stock at the option of the holder upon written notice. The Company allocates undistributed income (losses) attributable to common stock between the common stock classes on a one-to-one basis when computing net income (loss) per share. As a result, basic and diluted net income (loss) per share of voting and non-voting common stock are equivalent. Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common stock outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common stock outstanding during the period increased to include, if dilutive, the number of additional shares of common stock that would have been outstanding.

The Company generated a net loss in all periods presented, and therefore the basic and diluted net loss per share attributable to common stockholders is the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

Recently Adopted Accounting Standards

The Company implemented all new accounting pronouncements that are in effect and may have an impact on the condensed consolidated financial statements. Unless otherwise discussed, the Company believes the impact of any recently issued and not yet effective pronouncements will not have a material impact on the condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* (“ASU 2023-09”), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the income taxes paid information. ASU 2023-09 is effective for the Company for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company will adopt the guidance in its Form 10-K for the fiscal year ended December 31, 2025, which will result in additional disclosure in the notes to the consolidated financial statements..

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.

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. 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

As discussed in Note 1 - *Organization*, the Merger was accounted for as a reverse recapitalization in accordance with U.S. 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	4,263
Operating lease right-of-use assets, net	2,428
Other non-current assets	1,278
Accounts payable	(1,808)
Accrued expenses and other current liabilities	(11,365)
Lease liabilities, current	(3,701)
Lease liabilities, non-current	(1,658)
Other non-current liabilities	(1,092)
Net assets acquired	<u>\$ 83,036</u>

Legacy Inmagene incurred transaction costs related to the reverse recapitalization of \$9.4 million. This amount was recorded as a reduction to additional paid-in capital in the condensed consolidated statements of redeemable convertible preferred shares and stockholders' equity (deficit) for the three and nine months ended September 30, 2025.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured or disclosed at fair value by level within the fair value hierarchy (in thousands) as of September 30, 2025. There were no assets or liabilities measured at fair value as of December 31, 2024.

	Fair Value Measurements as of September 30, 2025			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market (cash equivalents)	\$ 34,638	\$ 34,638	\$ —	\$ —
Corporate debt securities (cash equivalents)	\$ 951	\$ —	\$ 951	\$ —
Corporate debt securities (marketable securities)	\$ 39,421	\$ —	\$ 39,421	\$ —
Promissory note	\$ 7,510	\$ —	\$ —	\$ 7,510
Total assets at fair value	<u>\$ 82,520</u>	<u>\$ 34,638</u>	<u>\$ 40,372</u>	<u>\$ 7,510</u>
Liabilities				
CVR liability	\$ 7,510	\$ —	\$ —	\$ 7,510
Total liabilities at fair value	<u>\$ 7,510</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,510</u>

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 and each period end, with changes recorded within other income (expense) on the statement of operations and comprehensive income (loss). 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 15% and 11.6% as of July 25, 2025 (inception date) and September 30, 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) on the statement of operations and comprehensive income (loss). The CVR liability and the Promissory Note have offsetting adjustments resulting from the change of their respective fair values as 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 following table presents the balances of the Promissory Note receivable and the corresponding CVR liability during the three and nine months ended September 30, 2025 (in thousands):

	Promissory Note Receivable	CVR Liability
Beginning Balance - January 1, 2025	\$ —	\$ —
Issuance - July 25, 2025	6,720	(6,720)
Change in fair value	790	(790)
Ending Balance - September 30, 2025	<u>\$ 7,510</u>	<u>\$ (7,510)</u>

During the nine months ended September 30, 2025, there were no transfers into or out of Level 3.

5. Marketable Securities

The following table summarizes the Company's available-for-sale securities as of September 30, 2025 (in thousands). There were no available-for-sale securities as of December 31, 2024.

	September 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Short-term Investments				
Corporate debt securities	\$ 39,327	\$ 95	\$ (1)	\$ 39,421
Total available-for-sale securities	<u>\$ 39,327</u>	<u>\$ 95</u>	<u>\$ (1)</u>	<u>\$ 39,421</u>

	Estimated Fair Value
Due in one year or less	\$ 24,860
Due after one year	14,561
Total available-for-sale securities	<u>\$ 39,421</u>

6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of September 30, 2025 and December 31, 2024, consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Prepaid research and development costs	\$ 1,879	\$ 57
Prepaid other	2,342	129
Other receivables	728	83
Prepaid foreign consumption tax	—	81
Prepaid expenses and other current assets	<u>\$ 4,949</u>	<u>\$ 350</u>

Other Non-Current Assets

Other non-current assets as of September 30, 2025 and December 31, 2024, consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Non-current deposits	\$ 4,951	\$ 69
Property and equipment, net	1	8
Investment in Celexor	—	942
Other non-current assets	<u>\$ 4,952</u>	<u>\$ 1,019</u>

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2025 and December 31, 2024, consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Accrued research and development costs	\$ 1,001	\$ 654
Accrued compensation	1,993	931
Accrued professional fees	407	485
Accrued financing cost	—	1,294
Accrued other	3,501	96
Accrued expenses and other current liabilities	<u>\$ 6,902</u>	<u>\$ 3,460</u>

Other Non-current Liabilities

Other non-current liabilities as of September 30, 2025 and December 31, 2024, consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Long-term taxes payable	1,056	—
Deferred rent	52	—
Other non-current liabilities	<u>\$ 1,108</u>	<u>\$ —</u>

7. Term Loan Advances

Concurrent with the execution of the Merger Agreement, Legacy Inmagene and Ikena entered into a Loan and Security Agreement (the “Loan Agreement”), pursuant to which Ikena agreed to loan the Company up to \$22.5 million in term loans of at least \$7.5 million (collectively, the “Term Loan Advances”), with the first Term Loan Advance occurring within three days of the execution of the Loan Agreement. Legacy Inmagene received the second Term Loan Advance of \$7.5 million in April 2025 and the third \$7.5 million Term Loan Advance in May 2025. The Term Loan Advances bore interest, on the outstanding daily balance thereof, at a rate of 6.0% per annum, and could have been prepaid at any time without a premium or a penalty. The Term Loan Advances were secured by all assets held or owned by Legacy Inmagene in respect of the anti-OX40 monoclonal antibody asset, IMG-007. The Term Loan Advances, including interest accrued therewith, was added to Ikena’s net cash for purposes of the Merger Agreement, including the calculation of the Exchange Ratio and the closing conditions.

Upon the consummation of the Merger on July 25, 2025, the outstanding principal balance from the Term Loan Advances of \$22.5 million and the corresponding accrued interest of \$0.5 million were forgiven.

8. Related Party Promissory Note Receivable and CVR Liability

As discussed in Note 1, as part of the Non-OX40 Divestiture, 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. 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.

As discussed in Note 4, the Promissory Note receivable is recorded at fair value at each period end. As of September 30, 2025, the Promissory Note receivable and related CVR liability were valued at \$7.5 million.

9. Preferred Shares

Legacy Inmagene previously issued convertible preferred shares and redeemable convertible preferred shares. All outstanding shares of the preferred shares of Legacy Inmagene were exchanged for the Company's common stock upon consummation of the

Merger on July 25, 2025. As a result, 3,158,303 shares of common stock of the Company were issued in connection with exchange of the preferred shares.

As of December 31, 2024, convertible preferred shares and redeemable convertible preferred shares consisted of the following (in thousands, except share and per share amounts):

	As of December 31, 2024				
	Shares Authorized	Shares Issued and Outstanding	Issuance price per share	Carrying Value	Liquidation Preference
Convertible preferred shares					
Series A	994,869	994,869	\$ 19.1085	\$ 18,967	\$ —
Total convertible preferred shares	994,869	994,869		\$ 18,967	\$ —
Redeemable convertible preferred shares					
Series Seed	217,923	217,923	\$ 2.2943	\$ 919	\$ 1,000
Series B	729,661	729,661	28.7119	28,966	29,943
Series C-1	885,407	825,708	73.4186	81,714	83,507
Series C-2	1,072,705	390,142	93.2153	47,440	49,125
Total redeemable convertible preferred shares	2,905,696	2,163,434		\$ 159,039	\$ 163,575

10. Common Stock

The Company's Amended and Restated Certificate of Incorporation, as amended, authorizes the Company to issue 150,000,000 shares of common stock, par value \$0.001 per share, consisting of 142,000,000 shares of voting common stock and 8,000,000 shares of non-voting common stock, par value \$0.001 per share. As of September 30, 2025, 10,650,956 shares of common stock and 530,716 shares of non-voting shares of common stock were issued and outstanding. Each share of voting common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote. The holders of voting and non-voting common stock are entitled to receive dividends, if any, as may be declared by the Company's Board of Directors.

As of September 30, 2025, the Company had reserved common stock for future issuances as follows:

	September 30, 2025
Outstanding common stock options (Note 11)	1,020,222
Shares available for grant under the 2025 Plan (Note 11)	1,018,732
Shares available for grant under the Inducement Plan (Note 11)	153,505
Shares available for issuance under the 2025 ESPP (Note 11)	111,816
Total	2,304,275

11. 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 from time to time (the "2021 Plan").

As of September 30, 2025, the Company granted stock options to purchase 99,435 shares of common stock under the 2025 Plan and there were 75,000 shares reserved for certain restricted stock unit awards ("RSUs") that have been approved and will be granted to certain employees upon the Company's filing of a Registration Statement on Form S-8 registering the shares of common stock issuable pursuant to the 2025 Plan. Additionally, there were 943,732 shares available for future grant under the 2025 Plan as of September 30, 2025.

In addition, the Company assumed, effective as of the closing of the Merger, the Legacy Inmagene 2019 Stock Incentive Plan (the “2019 Plan”), as well as the outstanding awards granted thereunder, the award agreements evidencing the grants of such awards and the remaining shares available under the 2019 Plan, in each case subject to applicable adjustments in the manner set forth in the Merger Agreement to such awards.

As of September 30, 2025, the Company granted stock options to purchase 484,707 shares of common stock under the 2019 Plan. Upon adoption of the 2025 Plan, no further grants will be made under the 2021 Plan or the 2019 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).

As of September 30, 2025, no offering periods under the 2025 ESPP have been initiated.

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).

As of September 30, 2025, the Company granted stock options to purchase 436,080 shares of common stock under the Inducement Plan and there were 153,505 shares reserved for certain restricted stock unit awards (“RSUs”) that have been approved and will be granted to the Company’s chief executive officer effective upon the Company’s filing of a Registration Statement on Form S-8 registering the shares of common stock issuable pursuant to the Inducement Plan.

Stock option valuation

The fair value of each award granted is estimated on the date of grant using the Black-Scholes-Merton option-pricing valuation model (the “Black-Scholes model”). In determining the fair value of stock options granted, the following weighted average assumptions were used for nine months ended September 30, 2025 and 2024:

	Nine Months Ended	
	September 30, 2025	September 30, 2024
Expected dividend yield	0.00%	0.00%
Expected volatility	102.60%	99.92%
Risk-free interest rate	4.03%	3.95%
Expected term (in years)	6.08	6.02

Summary of stock options

Legacy Inmagene granted stock options where vesting was subject to service and performance-based criteria, which were assumed by the Company upon the closing of the Merger. The service condition is typically a four-year service vesting period, and the exercise of the stock options was contingent upon consummation of certain transactions of Legacy Inmagene such as a change in control, corporate transaction, or initial public offering. A corporate transaction included specific events in which Legacy Inmagene underwent a merger or reverse merger (including the Merger), the sale of substantially all assets, a liquidation or dissolution, or an acquisition, resulting in either a change of control or the loss of majority voting power by its shareholders. Legacy Inmagene also granted certain stock options with vesting that is determined based on the achievement of certain corporate and individual milestones, which were assumed by the Company. The recognition of expense for these stock options is further dependent upon the achievement of certain milestones. In addition, the 2025 Plan allows for the acceleration of vesting of certain awards to the extent approved by the administrator of the 2025 Plan.

The Company's stock option activity for the nine months ended September 30, 2025 is summarized as follows:

	Shares	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	485,555	\$ 5.08		
Granted	536,430	15.22		
Exercised	(1,763)	22.68		
Cancelled/forfeited	—	—		
Outstanding as of September 30, 2025	<u>1,020,222</u>	\$ 10.41	7.88	\$ 2,897
Vested and expected to vest as of September 30, 2025	<u>1,020,222</u>	\$ 10.41	7.88	\$ 2,897
Exercisable as of September 30, 2025	<u>412,054</u>	\$ 4.42	5.26	\$ 2,610

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock as of September 30, 2025.

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2025 was \$12.48 per share.

Summary of RSUs

The following table summarizes RSU activity for the nine months ended September 30, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value (per share)
Unvested, beginning of period	—	\$ —
Granted	31,425	32.55
Vested	(31,425)	32.55
Forfeited	—	—
Unvested, end of period	<u>—</u>	<u>\$ —</u>

On April 8, 2025, Legacy Inmagene's Board of Directors granted RSU to employees. Prior to April 8, 2025, Legacy Inmagene had not granted any RSUs to employees. The RSUs contain service-based and performance-based vesting conditions. The performance-based vesting condition was the successful closing of the Merger. The service-based requirement was satisfied subject to the employee remaining in continuous service through the closing of the Merger. The holders of RSUs were not entitled to dividends or dividend equivalents. The fair value of the RSUs granted was based on the estimated fair value of the underlying shares at the date of grant.

Stock-based compensation expense for stock options

On July 25, 2025, upon consummation of the Merger, the performance condition of exercisability and vesting of the then outstanding stock-based awards were met where applicable. Consequently, the Company recorded \$14.9 million of stock-based compensation expense on the Closing Date.

Stock-based compensation expense for the nine months ended September 30, 2025 and 2024 was recorded as follows (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Research and development	\$ 10,062	\$ —
General and administrative	5,278	—
Total	<u>\$ 15,340</u>	<u>\$ —</u>

As of September 30, 2025, unrecognized stock-based compensation expense for stock option awards was \$7.5 million estimated to be recognized over a period of 3.6 years.

During the nine months ended September 30, 2024, the Company recorded \$14.0 million in research and development expense related to the issuance of common stock on the condensed consolidated statement of operations and comprehensive loss, respectively. See Note 13 for detail on the issuance of common stock related to the Hutchmed Agreement.

12. Commitments and Contingencies

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. The Company believes there is no litigation pending or loss contingencies that could have, either individually or in the aggregate, a material impact on the Company's condensed consolidated financial statements.

In connection with the merger, two actions have been 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").

The Company cannot predict the outcome of the Complaints or the Demands. The Company believes that the Complaints and the Demands are without merit, and the Company and the individual defendants intend to vigorously defend against the Complaints and the Demands and any subsequently filed similar actions. If additional similar complaints are filed or demands are received, absent new or significantly different allegations, the Company will not necessarily disclose such additional filings or demands.

Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

The Company enters into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore the Company believes that its non-cancelable obligations under these agreements are not material.

13. Collaborative Arrangements and Licensing Agreements

Licensing Agreements

Hutchmed Limited

On January 5, 2021, Legacy Inmagene entered into a Collaboration, Option and License Agreement (the "Hutchmed Agreement") with Hutchmed Limited ("Hutchmed"), formerly known as Hutchison MediPharma Limited. Legacy Inmagene entered into the Hutchmed Agreement as a strategic partnership to further develop four novel preclinical drug candidates discovered by Hutchmed for the potential treatment of multiple immunological diseases – OX40 (CD134) antagonistic monoclonal antibody (anti-OX40 mAb), BTK (Bruton tyrosine kinase) inhibitor (BTK HMPL-727), RIPK1 HMPL-662, and CSF-1R HMPL-958.

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").

Upon exercise of each License Option, Legacy Inmagene acquires 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") and is required pay a \$20.0 million fee per licensed compound, or, if exercise and payment is made within three years of execution of the Hutchmed Agreement, Legacy Inmagene may elect to pay

the option exercise fee in common stock pursuant to a share subscription agreement at a price to be agreed to by both parties. Following Legacy Inmagene's decision to exercise the License Option, 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. None of the payments under the Hutchmed Agreement are refundable.

In April 2023, Legacy Inmagene entered into an amendment to the Hutchmed Agreement which terminated portions of the Hutchmed Agreement related to the RIPK1 HMPL-662 compound, 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. Legacy Inmagene elected to pay Hutchmed the option exercise fee in the form of common stock pursuant to the Hutchmed Agreement. In February 2024, Legacy Inmagene and Hutchmed entered into a share subscription agreement whereby Legacy Inmagene agreed to issue 429,082 shares of common stock for satisfaction of the option exercise fees for the two licensed compounds. In the first quarter of 2024, Legacy Inmagene recorded \$14.0 million in research and development expenses on the condensed consolidated statements of operations and comprehensive loss.

The License Option rights to CSF-1R HMPL-958 were not exercised and have expired under the terms of the Hutchmed Agreement.

In connection with the Non-OX40 Divestiture, the BTK inhibitor program was sold to the BuyCo (Note 1). The Company became the successor of the Hutchmed Agreement upon consummation of the Merger, and continues to actively develop the anti-OX40 mAb program.

Legacy Collaborative Arrangements

Below is a summary of collaboration agreements and programs that have been divested in connection with the Non-OX40 Divestiture.

IMG-013 and IMG-008 Agreements

On July 12, 2024, Legacy Inmagene entered into separate exclusive license and collaboration agreements to license Legacy Inmagene's anti-IL-7Ra antibody (the "IMG-013 Agreement") and anti-IL-36R antibody (the "IMG-008 Agreement") to a third party. Legacy Inmagene determined that the IMG-008 Agreement and IMG-013 Agreement should be accounted for as separate contracts with a customer in accordance with ASC 606.

IMG-013 Agreement

Under the IMG-013 Agreement, Legacy Inmagene agreed to grant to a third party an exclusive royalty-bearing worldwide license to exploit patents, patent applications, and Legacy Inmagene know-how which would address immune disorders where Legacy Inmagene's anti-IL-7Ra antibody (IMG-013) is involved. The license term commenced upon receipt of the upfront payment and would continue until such time as there are no remaining payment obligations due to Legacy Inmagene.

Under the IMG-013 Agreement as amended by the settlement agreement and mutual general release pertaining to the IMG-008 Agreement, Legacy Inmagene was entitled to receive a \$3.5 million non-refundable upfront cash payment, which Legacy Inmagene received in the third quarter of 2024. Legacy Inmagene was eligible to receive additional payments under the IMG-013 Agreement based on development and regulatory milestones achievement, and based on sales-based milestones. Legacy Inmagene may also receive additional payments based on mid-single-digit sales-based royalties. None of the payments under the IMG-013 Agreement are refundable.

In order to determine the transaction price, Legacy Inmagene evaluated all the payments to be received during the duration of the contract. Fixed consideration exists in the form of the \$3.5 million upfront payment. Development, regulatory, and sales-based milestones and royalties were considered contingent variable consideration. Legacy Inmagene determined that the initial transaction price consisted of the upfront payment which is allocated to the one performance obligation. The transaction price allocated to the one performance obligation was recognized upon grant of license and transfer of technology in the third quarter of 2024.

IMG-008 Agreement

Under the IMG-008 Agreement, Legacy Inmagene agreed to grant to a third party an exclusive royalty-bearing worldwide license to exploit patents, patent applications, and Legacy Inmagene know-how which would address immune disorders where Legacy Inmagene's anti-IL-36R antibody (IMG-008) is involved. The license term would have commenced upon receipt of the upfront payment and would continue until such time as there are no remaining payment obligations due to Legacy Inmagene.

Under the IMG-008 Agreement, Legacy Inmagene was initially entitled to receive a \$6.5 million non-refundable upfront cash payment from IMG-008 no later than September 9, 2024. Legacy Inmagene was also eligible to receive additional payments based on achievement of development and regulatory milestones and sales-based milestones. Legacy Inmagene was also entitled to receive additional payments based on mid-single-digit sales-based royalties.

Legacy Inmagene and the third party entered into an amendment of the IMG-008 Agreement in the third quarter of 2024, whereby Legacy Inmagene extended the payment period for the upfront payment in exchange for a non-refundable \$0.7 million deposit. The \$0.7 million deposit was received by Legacy Inmagene in the third quarter of 2024 and was reflected as deferred revenue on the consolidated balance sheet as of December 31, 2024.

During the first quarter of 2025, Legacy Inmagene and the third party entered into a settlement agreement and mutual general release pertaining to the IMG-008 Agreement, whereby Legacy Inmagene agreed to dismiss all claims against the third party related to the IMG-008 Agreement in exchange for (1) re-affirmation of full release by the third party of the \$0.7 million of funds previously deposited by the third party; (2) payment of a one-time settlement amount of \$0.1 million by the third party to Legacy Inmagene; and (3) amendment of the above noted IMG-013 Agreement to increase the development and regulatory milestone fees. Except as so amended, the IMG-013 Agreement remains in full force and effect in accordance with its terms, whereas the IMG-008 Agreement is effectively terminated. During the first quarter of 2025, Legacy Inmagene recognized \$0.8 million of license revenue in the condensed consolidated statement of operations and comprehensive loss.

Telenor

On September 28, 2023, Legacy Inmagene entered into an exclusive license and collaboration agreement (the "Celexor Agreement") with Celexor Bio, Inc. ("Celexor"). Legacy Inmagene granted Celexor an exclusive royalty-bearing license to develop, manufacture, and commercialize any and all products and associated products utilizing Legacy Inmagene's IMG-018, a monoclonal antibody targeting immunoglobulin-like transcript 7. The license term commenced upon the execution of the Celexor Agreement and will continue until such time as there are no remaining payment obligations due to Legacy Inmagene.

Under the Celexor Agreement, Legacy Inmagene received an upfront payment of \$7.0 million and 1,223,300 shares of Series Seed-2 Preferred Shares of Celexor valued at \$0.9 million from Celexor. Legacy Inmagene was eligible to receive additional payments upon achievement of development and regulatory milestones and based on sales-based milestones. Legacy Inmagene could also receive additional payments based on mid-single-digit sales-based royalties. None of the payments under the Celexor Agreement were refundable. Legacy Inmagene determined the Celexor Agreement should be accounted for as a contract with a customer under ASC 606.

Legacy Inmagene concluded that the promises included the license of intellectual property and technology transfer, and these promises should be combined into a single performance obligation.

In order to determine the transaction price, Legacy Inmagene evaluated all of the payments to be received over the duration of the contract. Fixed consideration exists in the form of the upfront payment and Series Seed-2 Preferred Shares of Celexor received. Development, regulatory, and sales-based milestones and royalties were considered contingent variable consideration. Legacy Inmagene determined that the initial transaction price consisted of the upfront payment of \$7.0 million and the receipt of Series Seed-2 Preferred Shares of Celexor which were valued at \$0.9 million, which was allocated to the single performance obligation. The transaction price allocated to the single performance obligation was recognized upon grant of license and transfer of technology which occurred in 2023.

As of December 31, 2024, the Series Seed-2 Preferred Shares of Celexor were recorded within other non-current assets in the condensed consolidated balance sheets. The Celexor shares were included in the Non-OX40 divestiture and are no longer recorded within other non-current assets in the condensed consolidated balance sheet as of September 30, 2025.

Affibody

On April 29, 2020, Legacy Inmagene entered into a license and collaboration agreement (the “Affibody Agreement”) with Affibody AB (“Affibody”), under which Legacy Inmagene received an exclusive license to develop and commercialize any and all products and associated products utilizing ABY-035 in mainland China, Hong Kong, Taiwan, Macau, and South Korea (“Legacy Inmagene Territory”), a non-exclusive license to Affibody’s proprietary platform that is necessary or useful to develop and commercialize the licensed products in the Legacy Inmagene Territory and development activities in the Asia Pacific region, excluding Japan.

On January 9, 2025, Legacy Inmagene entered into an agreement with Affibody to terminate the Affibody Agreement effective as of January 10, 2025. In accordance with the terms of the Affibody Agreement, all corresponding licenses or sublicenses were terminated, and Legacy Inmagene agreed to wind down any ongoing studies for any compounds subject to the Affibody Agreement.

14. Net Loss per Share

The Company recast its basic and diluted earnings per share computations for the effect of the exchange ratio of 0.0030510 on its outstanding common stock and Series A preferred shares during the three and nine months ended September 30, 2025 and 2024, resulting from the close of the Merger which occurred on July 25, 2025.

Basic and diluted net loss per share attributable to common stockholders for the three months ended September 30, was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,	
	2025	2024
Numerator:		
Net loss	\$ (24,779)	\$ (3,183)
Less: accretion of redeemable convertible preferred shares	\$ (846)	\$ (2,998)
Net loss attributable to common stockholders - basic and diluted	<u>\$ (25,625)</u>	<u>\$ (6,181)</u>
Denominator:		
Weighted-average common stock outstanding	<u>8,526,781</u>	<u>1,400,557</u>
Weighted-average Series A convertible preferred shares outstanding	<u>270,345</u>	<u>994,869</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (2.91)</u>	<u>(2.58)</u>
Net loss per share attributable to Series A convertible preferred shareholders - basic and diluted	<u>\$ (2.91)</u>	<u>(2.58)</u>

Basic and diluted net loss per share attributable to common stockholders for the nine months ended September 30, was calculated as follows (in thousands, except share and per share amounts):

	Nine Months Ended September 30,	
	2025	2024
Numerator:		
Net loss	\$ (38,441)	\$ (31,756)
Less: accretion of redeemable convertible preferred shares	\$ (7,046)	\$ (8,757)
Net loss attributable to common stockholders - basic and diluted	<u>\$ (45,487)</u>	<u>\$ (40,513)</u>
Denominator:		
Weighted-average common stock outstanding	<u>3,808,867</u>	<u>1,121,742</u>
Weighted-average Series A convertible preferred shares outstanding	<u>750,707</u>	<u>994,869</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (9.98)</u>	<u>\$ (19.14)</u>
Net loss per share attributable to convertible preferred Series A shareholders - basic and diluted	<u>\$ (9.98)</u>	<u>\$ (19.14)</u>

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded potentially dilutive securities from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have had an anti-dilutive effect:

	As of September 30,	
	2025	2024
Series B redeemable convertible preferred shares (as converted to common stock)	—	729,666
Series C redeemable convertible preferred shares (as converted to common stock)	—	1,215,862
Series Seed redeemable convertible preferred shares (as converted to common stock)	—	217,928
Stock options to purchase common stock	<u>1,020,222</u>	<u>486,408</u>
Total	<u>1,020,222</u>	<u>2,649,864</u>

15. 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 also is reported on the consolidated statement of operations and comprehensive loss. The Company derives license revenue primarily in the United States from research and development collaborations and manages the business activities on a consolidated basis.

In addition, 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,	
	2025	2024	2025	2024
License Revenue	\$ —	\$ 3,500	\$ 800	\$ 3,500
Research and Development				
Clinical research and outside services	\$ 4,430	\$ 2,964	\$ 12,418	\$ 10,956
Compensation and related	1,123	921	2,771	3,226
Other research and development expenses(a)	—	—	—	14,168
Stock-based compensation expense	10,005	—	10,062	—
Total research and development expense	\$ 15,558	\$ 3,885	\$ 25,251	\$ 28,350
General and Administrative				
Compensation and related	\$ 1,046	\$ 567	2,374	2,076
Consulting and professional services	1,863	669	4,164	1,591
Other general and administrative expenses(b)	2,849	415	3,680	2,341
Stock-based compensation expense	5,278	—	5,278	—
Total general and administrative expense	\$ 11,036	\$ 1,651	\$ 15,496	\$ 6,008

- (a) Other research and development expenses include depreciation and amortization expense and a non-cash research and development expense for the common stock issuable pursuant to the Hutchmed Agreement of \$14.0 million for the nine months ended September, 2024.
- (b) Other general and administrative expenses include depreciation and amortization expense, and certain departmental expenses.

Property and equipment, net as of September 30, 2025, and December 31, 2024 was located in the United States.

16. Income Taxes

Income taxes for the three months ended September 30, 2025 and 2024 were recorded at the Company's estimated annual effective income tax rate, subject to adjustments for discrete events, if they occur. During the three and nine months ended September 30, 2025, the Company recorded a \$0.1 million income tax benefit. During the three and nine months ended September 30, 2024, the Company did not record any tax provisions. The primary reconciling items between the federal statutory rate of 21.0% and the Company's overall effective tax rate for these periods is due to net operating losses and the valuation allowance recorded against the full amount of the Company's net deferred tax assets and state taxes.

A valuation allowance is required when it is more likely than not that some portion or all of the Company's deferred tax assets will not be realized. The realization of deferred tax assets depends on the generation of sufficient future taxable income during the period in which the Company's related temporary differences become deductible. Management believes that based on the earnings history of the Company, it is more likely than not that the benefits of these assets will not be realized, and therefore, a full valuation allowance has been recorded against the Company's net deferred tax assets as of September 30, 2025, and December 31, 2024.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions, most notably Section 174 capitalization of domestic research and development costs. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. There was not a significant impact on the Company's tax expense or effective tax rate for the three or nine months ended September 30, 2025 associated with the OBBBA. The OBBBA is not expected to have a material impact on the 2025 consolidated financial statements.

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 on Form 10-Q (this "Quarterly Report") and the audited financial statements and the related notes and the discussion under the heading "Inmagene Biopharmaceuticals' Management's and Discussion and Analysis of Financial Condition and Results of Operations" in our Registration Statement on Form S-1 (the "Registration Statement"), filed with the Securities and Exchange Commission (the "SEC") on September 8, 2025 and declared effective on September 15, 2025. 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 the Registration Statement, 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. Unless otherwise stated or the context otherwise requires, the references to the "Company," "we," "our," or "us" refer to Inmagene Biopharmaceuticals together with its consolidated subsidiaries prior to the Merger and to ImageBio, Inc. together with its consolidated subsidiaries following the Merger, references to "Ikena" refer to Ikena Oncology, Inc. prior to the Merger, references to "Legacy Inmagene" refer to Inmagene Biopharmaceuticals together with its consolidated subsidiaries prior to the Merger and references to "common stock" refer to the Company's voting and non-voting shares of common stock for periods following the Merger and to Legacy Inmagene's ordinary shares for periods prior to the Merger.

Overview

We are a clinical-stage biopharmaceutical company developing therapeutics for patients with immunological, autoimmune and inflammatory diseases. Our lead asset IMG-007 is a non-depleting anti-OX40 monoclonal antibody which binds specifically to OX40 receptor on activated T cells to block their binding to OX40 ligand ("OX40L"). IMG-007 is being developed to potentially treat multiple autoimmune and inflammatory diseases and disorders, with initial evaluation in atopic dermatitis ("AD"). In our Phase 1b/2a clinical proof of concept ("POC") trial, four-week treatment with IMG-007 resulted in marked clinical activity which sustained up to 24 weeks based on multiple outcome measures. In addition, durable inhibition of serum inflammatory markers of diverse T helper ("Th") cells, including Th1, Th2 and Th17 cells was observed. IMG-007 was well-tolerated overall. The cumulative clinical and pharmacodynamic activity of IMG-007 coupled with the safety profile observed to date support further clinical development.

Autoimmune and inflammatory diseases have a large and growing unmet medical need affecting hundreds of millions of patients worldwide. The global immunology market is expected to grow from approximately \$103 billion in 2024 to approximately \$257 billion by 2032. Many of these diseases are chronic, highly symptomatic, and occur in both children and adults, indicating debilitating symptoms can occur in patients for many years, or throughout their entire lives. Numerous immunological diseases have overlapping pathogenic mechanisms, often rooted in inflammation and autoimmune reactions. Accordingly, therapeutics for such diseases have often been developed for multiple different disease indications. For example, Humira®, which targets TNFα, is approved and utilized at least nine indications in the U.S., including rheumatoid arthritis, Crohn's disease, and plaque psoriasis, while Skyrizi®, which targets IL-23, is approved and used in four indications, including psoriatic arthritis, plaque psoriasis, and ulcerative colitis. These types of molecularly targeted products have become pipelines within themselves, serving a wide range and large numbers of patients, who tend to be treated chronically, and expanding to become revenue franchises.

IMG-007 targets the OX40 receptor and is initially being developed for the treatment of AD with the potential to grow into a "pipeline within a product" for the treatment of various immunological, autoimmune and inflammatory conditions. We believe IMG-007 has the potential to demonstrate a differentiated clinical profile from other AD therapies. In our Phase 1b/2a AD study, 54% of patients achieved EASI-75 (75% reduction in eczema area and severity index) at Week 20 after only three treatments. Out of all 13 treated patients there were no serious adverse events, and no patients experienced pyrexia and chills. A Phase 2b dose-finding AD study was initiated in mid-2025 and dosing of patients is underway, and we plan to submit a protocol amendment to expand the number and exposure range of dosing regimens studied to fully characterize the clinical profile of IMG-007 in the near term. Topline data from the Phase 2b clinical trial is expected in 2027.

OX40 signaling is thought to be important in driving the pathogenesis of a wide spectrum of immunological, autoimmune and inflammatory diseases including dermatological, respiratory, gastrointestinal, and rheumatic diseases, and we intend to explore additional indications with IMG-007 including alopecia areata ("AA"), asthma, and chronic obstructive pulmonary disease ("COPD").

Recent Developments

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, an exempted company with limited liability incorporated and existing under the laws of the Cayman Islands (“Legacy Inmagene”), in accordance with the terms of the Agreement and Plan of Merger (the “Merger Agreement”), dated as of December 23, 2024, 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 (with the “Second Merger” and, together with the First Merger, the “Merger”). Also on July 25, 2025, Ikena changed its name from “Ikena Oncology, Inc.” to “ImageneBio, Inc.”

At the effective time of the First Merger (the “First Effective Time”), (i) each ordinary share and preferred share of Legacy Inmagene (each such share, an “Legacy Inmagene Share”) held as treasury shares 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, par value \$0.001 per share (“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. In connection with the Merger, Ikena issued an aggregate of 4,601,375 shares of Ikena Common Stock to Legacy Inmagene shareholders. Following the Reverse Stock Split (as defined below), the Merger and the PIPE Financing (defined below) a total of 11,181,672 shares of common stock of the Company were outstanding.

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Under this method of accounting, Legacy Inmagene was deemed to be the accounting acquirer for financial reporting purposes. This determination was 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. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of pre-Merger Legacy Inmagene issuing stock to acquire the net assets of Ikena, and (ii) the reported historical operating results of the Company prior to the Merger are those of Legacy Inmagene. Additional information regarding the Merger is included in Note 3 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Reverse Stock Split

Immediately prior to the First Effective Time, Ikena effected a 1-for-12 reverse stock split of its issued Ikena Common Stock, which became effective on July 25, 2025 (the “Reverse Stock Split”). The shares of Ikena Common Stock traded on The Nasdaq Global Market through the close of business on Friday, July 25, 2025, under the ticker symbol “IKNA.” Following the Merger, the shares of the Company’s common stock commenced trading on The Nasdaq Capital Market on a post-Reverse Stock Split adjusted basis under the ticker symbol “IMA” on July 28, 2025.

All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock and preferred share data, per share data, and related information contained in the 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.

PIPE Financing

Concurrently with the execution of the Merger Agreement, Ikena entered into subscription agreements (the “Subscription Agreements”) with certain accredited investors (the “PIPE Investors”), pursuant to which, immediately following the closing of the Second Merger, the PIPE Investors subscribed for and purchased, and Ikena issued and sold, an aggregate of 2,508,339 shares of Ikena Common Stock in a private placement at a price of approximately \$29.90 per share for aggregate gross proceeds of approximately \$75.0 million (the “PIPE Financing”).

The Non-OX40 Divestiture

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 us immediately prior to the Merger (the “Non-OX40 Divestiture”). Specifically, we sold and transferred (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 (“BuyCo”) held by the holders of outstanding Legacy Inmagene Shares prior to the Merger, purchased from us 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 us. 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. The promissory note matures on the earlier of (i) the year 2035 or (ii) the date on which we declare 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 made under the promissory note from BuyCo 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, a non-depleting anti-OX40 monoclonal antibody, for the treatment of AD and other potential indications, became the only product candidate we have in clinical development.

Transition Services Agreement

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 operations of our 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, bioanalytics and pharmacovigilance (collectively, the “Miragene Services”). The initial term of the Transition Services Agreement is six months (the “Initial Term”), which would have been automatically extended for an additional six months if we did not provide written notice to terminate within the first three months of the Initial Term. In addition, we may extend the Initial Term with respect to any or all of the Miragene Services for up to an additional 12 months upon a 60-day written notice prior to the end of the Initial Term. Upon the closing of the Merger, we paid Miragene \$1.25 million as a prepayment for the services to be provided during the Initial Term. On October 23, 2025, we provided written notice to Miragene of our 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 of the Transition Services Agreement for certain Miragene Services for aggregate service fees in the amount of \$0.2 million.

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.

Operating Expenses

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

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the research and development of our programs. These expenses 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;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies;
- license and sub-license fees; and
- gains and losses on disposal of research and development property and equipment.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as research and development prepaid expenses on our condensed consolidated balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or services are performed. The successful development of any future product candidates is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that would be necessary to complete the potential development and commercialization of any future product candidates.

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, operations, human resources, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to corporate matters and patent-related activities, allocated facilities and other 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 IMG-007 and any future product candidates, as well as expand our operations and begin operating as a public company following the Merger. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with the Nasdaq listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest (Expense) Income

Interest (expense) income consists of the accrued interest on the Term Loan Advances (as defined in Note 7 to our condensed consolidated financial statements included elsewhere in this Quarterly Report) from Ikena to us and interest earned on cash, cash equivalents and marketable securities.

Other Income, Net

Other income, net primarily relates to government assistance in the form of grants for qualifying property and equipment, and gains and losses resulting from foreign currency transactions which are denominated in currencies other than the functional currency.

Income Taxes

We recorded an income tax benefit of \$0.1 million during the nine months ended September 30, 2025. There was no income tax provision for the nine months ended September 30, 2024. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date, as we believe that it is not more likely than not that no benefit will be realized due to the cumulative losses generated to date and expectation of future losses.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and September 30, 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,			
	2025	2024	Change \$	Change %
License revenue	\$ —	\$ 3,500	\$ (3,500)	(100)%
Operating expenses:				
Research and development	15,558	3,885	11,673	300%
General and administrative	11,036	1,651	9,385	- 568%
Total operating expenses	26,594	5,536	21,058	380%
Loss from operations	\$ (26,594)	\$ (2,036)	(24,558)	1,206%
Other income (expense):				
Interest (expense) income	(96)	46	(142)	(309)%
Other income (expense), net	1,837	(1,193)	3,030	- (254)%
Total other income (expense), net	1,741	(1,147)	2,888	(252)%
Loss before income taxes	\$ (24,853)	\$ (3,183)	(21,670)	681%
Income tax benefit	(74)	—	(74)	(100)%
Net loss	<u>\$ (24,779)</u>	<u>\$ (3,183)</u>	<u>\$ (21,596)</u>	<u>678%</u>

License Revenue

There was no license revenue for the three months ended September 30, 2025. License revenue for the three months ended September 30, 2024 was from a non-refundable payment from the IMG-013 Agreement (Note 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report).

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2025 were \$15.6 million compared to \$3.9 million for the three months ended September 30, 2024. The increase of \$11.7 million was primarily due to a \$10.0 million increase in stock based compensation, an increase of \$0.6 million in compensation costs and a \$0.8 million increase related to clinical program development.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2025 were \$11.0 million compared to \$1.7 million for the three months ended September 30, 2024. The increase of \$9.3 million was primarily due to a \$5.2 million increase in stock based compensation, an increase of \$1.0 million in compensation costs, a \$1.3 million increase in professional services costs, and a \$0.2 million increase in insurance expense.

Interest Income (Expense)

Interest income (expense) for the three months ended September 30, 2025 was \$0.1 million compared to interest income of \$46,000 for the three months ended September 30, 2024. The increase of \$0.1 million was primarily due to interest expense recorded on the initial Term Loan Advance, which was borrowed in December 2024.

Other Income (Expense), Net

Other income, net for the three months ended September 30, 2025 was \$1.8 million was primarily related to a \$1.2 million of interest and dividend income from the available-for-sale securities, and \$0.3 million of sublease income. Other expense, net of \$1.1 million for the three months ended September 30, 2024 was primarily due to a loss on disposal of property and equipment.

Comparison of the Nine Months Ended September 30, 2025 and September 30, 2024

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,			
	2025	2024	Change \$	Change %
License revenue	\$ 800	\$ 3,500	\$ (2,700)	(77)%
Operating expenses:				
Research and development	25,251	28,350	(3,099)	(11)%
General and administrative	15,496	6,008	9,488	- 158%
Total operating expenses	40,747	34,358	6,389	19%
Loss from operations	(39,947)	(30,858)	(9,089)	29%
Other income (expense):				
Interest (expense) income	(409)	344	(753)	(219)%
Other expense, net	1,841	(1,242)	3,083	- (248)%
Total other (expense) income, net	1,432	(898)	2,330	(259)%
Loss before income taxes	(38,515)	(31,756)	(6,759)	21%
Income tax benefit	(74)	—	(74)	(100)%
Net loss	<u>\$ (38,441)</u>	<u>\$ (31,756)</u>	<u>\$ (6,685)</u>	<u>21%</u>

Licensing Revenue

Licensing revenue for the nine months ended September 30, 2025 was \$0.8 million which resulted from a non-refundable payment from the IMG-008 Agreement. License revenue for the nine months ended September 30, 2024 was \$3.5 million from a non-refundable payment from the IMG-013 Agreement (Note 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report).

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2025 were \$25.3 million compared to \$28.4 million for the nine months ended September 30, 2024. The decrease of \$3.1 million is a result of a \$14 million decrease in research and development expense related to the exercise of our option under the Hutchmed Agreement in the prior year, offset by an increase of \$10.1 million in stock based compensation, and an increase of \$0.4 million related to clinical program development.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2025 was \$15.5 million compared with \$6.0 million for the nine months ended September 30, 2024. The increase of \$9.5 million was primarily due to a \$5.3 million increase in stock based compensation, an increase of \$0.7 million compensation costs, a \$2.6 million increase in professional services costs, and \$0.3 million in insurance expense.

Interest (Expense) Income

Interest expense for the nine months ended September 30, 2025 was \$0.4 million compared to interest income of \$0.3 million for the nine months ended September 30, 2024. The increase of \$0.7 million was primarily due to \$0.5 million of interest expense recorded on the initial Term Loan Advance, which was borrowed in December 2024, and a decrease of \$0.3 million of interest income due to reduced account balances compared to the prior year.

Other Income (Expense), Net

Other income, net for the nine months ended September 30, 2025 was \$1.8 million was primarily related to a \$1.2 million of interest and dividend income from the available-for-sale securities, and a \$0.3 million of sublease income. Other expense, net of \$1.2 million for the nine months ended September 30, 2024 was primarily due to a loss on disposal of property and equipment.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred recurring losses and negative cash flows from operations since our inception. For the nine months ended September 30, 2025, we incurred a net loss of \$38.4 million and used \$40.6 million of cash in operating activities. As of September 30, 2025, we had an accumulated deficit of \$223.1 million and cash, cash equivalents and marketable securities of \$142.6 million.

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. Current and future programs will require significant research and development efforts, including preclinical and clinical trials, and regulatory approvals for commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. If we obtain regulatory approval for any of our product candidates and start to generate revenue, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

Concurrent with the execution of the Merger Agreement, Ikena entered into the Subscription Agreements with the PIPE Investors, pursuant to which, immediately following the closing of the Second Merger, the PIPE Investors subscribed for and purchased, and Ikena issued and sold, an aggregate of 2,508,339 shares of Ikena Common Stock in a private placement at a price of approximately \$29.90 per share for aggregate gross proceeds of approximately \$75.0 million. The net proceeds from the PIPE Financing are expected to advance our discovery and clinical phase pipeline, business development activities, working capital, and other general corporate purposes.

Concurrent with the execution of the Merger Agreement, Legacy Inmagene and Ikena entered into a Loan and Security Agreement (the "Loan Agreement"), pursuant to which Ikena agreed to lend up to \$22.5 million in Term Loan Advances in increments of at least \$7.5 million, subject to certain drawdown conditions, of which the first advance of \$7.5 million was funded in December 2024. In April 2025, we received a second advance of \$7.5 million and in May 2025, we received the third advance of \$7.5 million (see Note 7 to our condensed consolidated financial statements included elsewhere in this Quarterly Report). The Term Loan Advances bore interest, on the outstanding daily balance thereof, at a rate equal to 6.0% per annum. The Term Loan Advances were secured by all assets of Legacy Inmagene and its subsidiaries in respect of anti-OX40 monoclonal antibody asset, IMG-007. Upon consummation of the Merger on July 25, 2025, all obligations under the Loan Agreement were automatically forgiven in accordance with provisions contained therein.

We believe that our existing cash, cash equivalents and marketable securities are sufficient to support operations through at least the next 12 months from the date of issuance date of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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. 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, government or private party grants, 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.

Comparison of the Nine months ended September 30, 2025 and September 30, 2024

The following table sets forth a summary of the net cash flow activity for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	\$ (40,626)	\$ (17,844)
Net cash provided by investing activities	(4,450)	11,020
Net cash provided by financing activities	135,468	—
Effects of exchange rates on cash and cash equivalents	652	117
Net increase (decrease) in cash and cash equivalents	<u>\$ 91,044</u>	<u>\$ (6,707)</u>

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2025 was \$40.6 million, consisting primarily of net loss incurred during the period of \$38.4 million and a net change of \$18.3 million in our operating assets and liabilities, partially offset by non-cash charges of \$16.1 million. The non-cash charges included \$15.3 million of stock-based compensation, \$0.5 million in non-cash interest expense and \$0.5 million of amortization of right-of-use assets. The net change in operating assets and liabilities primarily related to a \$3.6 million increase in prepaid expenses and other current assets, a \$1.3 million increase in other non-current assets, a \$2.2 million decrease in accounts payable, a \$9.9 million decrease in accrued expenses and other current liabilities, a \$0.7 million decrease in operating lease liabilities, and a \$0.7 million decrease in deferred revenue.

Net cash used in operating activities for the nine months ended September 30, 2024, was \$17.8 million, consisting primarily of net loss incurred during the period of \$31.8 million and a net change of \$2.8 million in our operating assets and liabilities, partially offset by \$16.7 million in non-cash charges. The non-cash charges included \$14.0 million of non-cash research and development expense for the commitment of common stock related to the Hutchmed Agreement, \$1.1 million in depreciation and amortization, a loss on disposal of property and equipment of \$1.3 million, and \$0.3 million of amortization of right-of-use assets. The net change in operating assets and liabilities primarily related to a \$0.7 million decrease in accrued expenses and other current liabilities, a \$0.3 million decrease in operating lease liabilities, a \$2.2 million decrease in accounts payable, and \$0.2 million increase in prepaid expenses and other current assets, partially offset by a \$0.7 million increase in deferred revenue and a \$0.1 million decrease in other non-current assets.

Investing Activities

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

Net cash provided by investing activities for the nine months ended September 30, 2024 was \$11.0 million, primarily due to \$10.2 million of cash proceeds from maturities and sales of available-for-sale securities, and \$0.8 million of proceeds from sale of property and equipment.

Financing Activities

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

Net cash provided by financing activities for the nine months ended September 30, 2024 was zero.

Contractual Obligations and Other Commitments

We have entered into contracts in the normal course of business with suppliers, CROs, CMOs, and clinical trial sites. These agreements provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancelable obligations under these agreements as of the nine months ended September 30, 2025.

We have milestones, royalties and/or other payments due to third parties under our existing license and collaboration agreements and the Ikena CVR Agreement and Legacy Inmagene CVR Agreement (each as defined in Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report). See Notes 1 and 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report. We cannot estimate when such payments will be due, and none of these events were probable to occur as of September 30, 2025.

Lease Obligations

As of September 30, 2025, we had two existing leases for office facilities in the United States. These leases are classified as operating lease agreements that expire at various dates from November 2025 through April 2027. Our leases do not include options to terminate prior to the expiration date.

The lease agreement contains scheduled rent increases over the lease term. Under the terms of the lease agreements, we are responsible for certain property management fees, taxes, and common area maintenance expenses.

Future minimum commitments under these leases are \$3.5 million as of September 30, 2025 of which \$2.2 million is due in less than 12 months, and \$1.3 million is due in greater than 12 months.

Term Loan

Under the Loan Agreement, we drew down the first tranche of \$7.5 million in December 2024, the second tranche of \$7.5 million was taken in April 2025 and the third tranche of \$7.5 million was taken in May 2025. The Term Loan bore interest, on the outstanding daily balance thereof, at a rate of 6.0% per annum, and could have been prepaid at any time without premium or penalty.

Upon consummation of the Merger, all unpaid balances of the Term Loan, including the loan principal of \$22.5 million and accrued but unpaid interest of \$0.5 million, were automatically forgiven.

Critical Accounting Estimates

Our discussion and analysis of our results of operations and liquidity and capital resources are based on our condensed consolidated financial statements which have been prepared in accordance with U.S. GAAP. Our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and the related disclosures of contingent liabilities in our condensed consolidated financial statements and accompanying notes. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ significantly from these estimates under different assumptions, judgments or conditions.

Revenue Recognition

We recognize revenue in accordance with ASC 606, Revenue from Contracts with Customers (“ASC 606”), which applies to all contracts with customers, except for elements of certain contracts that are within the scope of other standards, such as collaboration arrangements.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. A customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity’s ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps:

- (i) Identify the contract(s) with a customer;
- (ii) Identify the performance obligations in the contract, including whether they are distinct;
- (iii) Determine the transaction price, including the constraint on variable consideration;
- (iv) Allocate the transaction price to the performance obligations in the contract; and
- (v) Recognize revenue when (or as) we satisfy each performance obligation.

We only apply the five- step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. A performance obligation is a promise in an agreement to transfer a distinct good or service to the customer. If a promised good or service is not distinct, it is combined with other promised goods or services into a performance obligation.

The total consideration which we expect to collect in exchange for our goods or services is an estimate and may be fixed or variable. We constrain the estimated variable consideration when we assess it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The transaction price is re-evaluated, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. Revenue is recognized when performance obligations in the contracts are satisfied, in the amount reflecting the expected consideration to be received from the goods or services transferred to the customers.

Consideration received in advance is recorded as deferred revenue and is recognized when or as the related performance obligation is satisfied. The principal activities from which we generate revenue include licensing agreements and collaboration agreements. License revenue primarily represents amounts earned under agreements that license our intellectual property to other companies. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and royalties based on net sales of approved products. Collaboration revenue primarily represents amounts earned under strategic collaboration arrangements with third parties for research and other licenses, development, and commercialization of certain product candidates. Under such arrangements, consideration typically includes fixed consideration in the form of an upfront payment and variable consideration in the form of potential development, regulatory, and commercial milestone payments, license fees, funding of research and development services and preclinical and clinical material, and royalties on net sales of licensed products. See Note 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Research and Development Expenses

Our research and development expenses include estimates of our expenses resulting from obligations under contracts with vendors, consultants and CROs in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our condensed consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. We determine clinical trial cost estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel and outsider service providers as to the progress of studies or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from estimates on a cumulative catch-up basis.

Stock-Based Compensation

We measure stock-based compensation expense for all stock-based awards with service-based and performance-based vesting conditions at the grant date based on the fair value measurement of the award. Compensation expense for service-based awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing when achievement of the performance condition becomes probable. Expense is adjusted for actual forfeitures of unvested awards as they occur. Prior to the Merger, we calculated the fair value measurement of share options using the Black-Scholes-Merton option-pricing valuation model ("Black-Scholes model"). The Black-Scholes model requires the use of subjective and complex assumptions, which determine the fair value of stock-based awards, including the option's expected term and the price volatility of the underlying shares. We calculate the fair value of options granted by using the Black-Scholes model with assumptions below.

- Fair value of common stock: Because Legacy Inmagene's common stock was not publicly traded prior to the Merger, the fair value of our common stock prior to the Merger was determined on a periodic basis, as determined by the Legacy Inmagene board of directors, with the assistance of an independent third-party valuation expert. These valuations were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Technical Practice Aid (Valuation of Privately-Held-Company Equity Securities Issued as Compensation). The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment. Management considered, among other things, our business, financial condition and results of operations, including related industry trends affecting our operations; the likelihood of achieving a liquidity event, such as an initial public offering, or sale, given prevailing market conditions; the lack of marketability of our common stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions. Subsequent to the Merger, our common stock is publicly traded.
- Risk-free interest rate: We base the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.
- Expected volatility: Because Legacy Inmagene did not have any trading history for its common stock prior to the Merger, the expected volatility assumption was based on volatilities of a peer group of similar companies whose share prices were publicly available. The peer group was developed based on companies in the clinical stage biopharmaceutical industry.

- Expected term: The expected term represents the period of time that options are expected to be outstanding. Because we do not have historical exercise behavior, it determines the expected term assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.
- Expected dividend yield: We base the expected dividend yield assumption on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Recent Accounting Pronouncements

For this information, refer to Note 2 of our condensed consolidated financial statements included elsewhere 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 interim 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 interim principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025, the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and interim principal financial officer have concluded that the Company’s disclosure controls and procedures were not effective as a result of a material weakness that existed in Legacy Inmagene’s internal control over financial reporting as described below.

Material Weakness in Internal Control over Financial Reporting

In connection with the preparation of Legacy Inmagene’s financial statements for the years ended December 31, 2024 and 2023, a material weakness was identified in its 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.

Legacy Inmagene 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 Legacy Inmagene’s financial statements.

However, this material weakness could result in a misstatement of substantially all of the Legacy Inmagene 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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings.

In connection with the proposed merger, two actions have been 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”).

The Company cannot predict the outcome of the Complaints or the Demands. The Company believes that the Complaints and the Demands are without merit, and the Company and the individual defendants intend to vigorously defend against the Complaints and the Demands and any subsequently filed similar actions. If additional similar complaints are filed or demands are received, absent new or significantly different allegations, the Company will not necessarily disclose such additional filings or demands.

Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

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,” you should consider carefully the risks and uncertainties described below, 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 you could lose all or part of your 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 IMG-007. We have not yet demonstrated an ability to successfully manufacture, obtain marketing approvals for or commercialize IMG-007. 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, 2025 and the year ended

December 31, 2024, our net losses were \$38.4 million and \$36.6 million, respectively. As of September 30, 2025, we had an accumulated deficit of \$223.1 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 IMG-007 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 IMG-007 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 IMG-007 and any future product candidates in our desired jurisdictions, successfully manufacture IMG-007 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 and/or to modify any of our manufacturing processes or make other changes to IMG-007 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, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. If we are unable to develop, obtain regulatory approval, and successfully commercialize IMG-007 or any future product candidate either alone or with collaborators, or if revenues from IMG-007 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 IMG-007 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 IMG-007 and any future product candidate into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize IMG-007 and any future product candidate, if approved. In addition, as IMG-007 progresses through development and toward commercialization, we will need to make certain milestone payments to HUTCHMED Limited (formerly known as Hutchinson Medipharma Limited) ("Hutchmed") under a collaboration, option and license agreement with Hutchmed (as amended, the "Hutchmed Agreement") and tiered royalties from commercial sales of IMG-007, 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 IMG-007 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. As of September 30, 2025, our cash and cash equivalents were \$103.2 million. Because the length of time and activities associated with successful development of IMG-007 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 IMG-007 and any future product candidates;
- the costs and timing of manufacturing for IMG-007 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 IMG-007 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 our current or 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 IMG-007 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, 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our equity securities. 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 IMG-007 for the treatment of AD and for other potential indications.

On July 25, 2025, immediately prior to consummation of the Merger, Legacy Inmagene consummated 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. Accordingly, our business is entirely dependent on the success of IMG-007 for the treatment of AD and other potential indications. IMG-007 is currently in Phase 2 development for the treatment of moderate-to-severe AD. We may also develop IMG-007 for other immunological, autoimmune and inflammatory diseases such as alopecia areata, asthma and COPD. We cannot give any assurance that we will generate preclinical, clinical or other data for IMG-007 for the treatment of AD or other immunological, autoimmune and inflammatory diseases sufficiently supportive to receive regulatory approval, which will be required before IMG-007 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 IMG-007. IMG-007 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 IMG-007, which may never occur. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize IMG-007, 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 IMG-007 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 you or 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, IMG-007 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. IMG-007 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 IMG-007 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 IMG-007 and any future product candidates. Before obtaining regulatory approvals for the commercial sale of any of IMG-007 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 IMG-007 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. IMG-007 and each 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates.

To date, we have not completed any pivotal clinical trials required for the approval of IMG-007. 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 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 GCP requirements, or applicable regulatory guidelines in other countries;
- 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates for various reasons, including non-compliance with regulatory requirements, a finding that IMG-007 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 IMG-007 or any future product candidates;

- the cost of clinical trials of IMG-007 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 IMG-007 or any future product candidates or other materials necessary to conduct clinical trials of IMG-007 or any future product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving IMG-007 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 IMG-007 or any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of IMG-007 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 IMG-007 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 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.

IMG-007 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 IMG-007 or any future product candidates and submit a BLA or MAA for regulatory approval of IMG-007 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 IMG-007 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 IMG-007 or any future product candidates could be harmed, and our ability to generate revenues from IMG-007 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 revenues. 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 IMG-007 or any future product candidates.

IMG-007 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.

There may be undesirable side effects and adverse events associated with IMG-007 or any future product candidates. Undesirable side effects or adverse events that may be caused by IMG-007 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.

While the data reported to date from our Phase 1 and Phase 2a clinical trials indicate that IMG-007 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 IMG-007.

If unacceptable treatment-related side effects or deaths arise in the development of IMG-007 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 or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 for the treatment of AD 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 CDMOs or require us to identify new CDMOs 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 IMG-007 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. IMG-007 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 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 pre-clinical 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 IMG-007 or any future product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for IMG-007 or any future product candidates.

We select the indications for the development of IMG-007 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 IMG-007 or any future product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for IMG-007 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 IMG-007 for the treatment of AD. 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, including the current shutdown which is ongoing. 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 the current shutdown continues or another prolonged government shutdown occurs and/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, the current or any future government shutdowns and/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 IMG-007 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 IMG-007 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. 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.

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 IMG-007 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 IMG-007 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 IMG-007 for AD and other potential indications. We license rights to IMG-007 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 IMG-007 pursuant to the license agreement (the “Cell Line License Agreement”) and may enter into future licenses or other intellectual property-related agreements for IMG-007 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 IMG-007 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 IMG-007 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 IMG-007, Hutchmed will be eligible to receive from us certain milestone payments and tiered royalties from commercial sales of IMG-007, 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 IMG-007 and/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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007, 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 IMG-007 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 from for IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 or other product candidates could be adversely affected.

Our rights to develop and commercialize IMG-007 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 IMG-007. 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 IMG-007. 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 IMG-007. 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 IMG-007, 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 IMG-007 for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of IMG-007 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of IMG-007 and any future product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if IMG-007 or any future product candidates that receive marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Our active pharmaceutical ingredients and drug product for IMG-007 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 House of Representatives of the prior Congress (the “118th Congress”) passed the BIOSECURE Act, which proposed prohibiting U.S. government contracts, grants, and loans to entities that use equipment and services from certain named Chinese biotech companies, which included WuXi AppTec and WuXi Biologics and certain of their respective subsidiaries and affiliates, and would authorize the U.S. government to include additional Chinese biotechnology companies of concern. This version of the BIOSECURE Act included a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. On October 9, 2025, the Senate of the current Congress (the “119th Congress”) passed its version of the National Defense Authorization Act (“NDAA”) for Fiscal Year 2026, which includes an amendment prohibiting contracting with certain biotechnology providers. While the amendment includes the same general prohibitions around government funding, contracts, and grants to certain biotechnology companies and entities which contract with such companies, there are certain differences from the versions of the BIOSECURE Act proposed by the prior 118th Congress. Rather than explicitly naming the companies of concern, the amendment defines a “biotechnology company of concern” as an entity that is identified on the annual 1260H List of Chinese military companies (the “1260H List”) issued by the U.S. Department of Defense, any entity designated by the U.S. Government, and certain subsidiaries, parents, affiliates, and successors of the foregoing. In addition, the amendment provides a grandfathering period of five years for entities that are designated by the U.S. Government; however, entities identified on the 1260H List are not eligible for such grandfathering period. The House and Senate of the current Congress will need to reconcile their respective versions of the NDAA and therefore it is possible for the language to further change and be amended, or even for the amendment to be removed from the final reconciled version of the NDAA. In addition, the Trump administration’s recent and evolving tariffs imposed on imports from China as well as China’s retaliatory tariffs on U.S. goods are expected to 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. We currently have no plans to pursue contracts with alternative suppliers or manufacturers outside of China for our active pharmaceutical ingredients and drug product for IMG-007. Accordingly, there is a risk that, if supplies

are interrupted, or the quality of ingredients provided by our single source provider is not to our specification or higher tariffs are imposed on Chinese goods, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could materially harm our business.

Furthermore, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA 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 IMG-007 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 IMG-007 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. In addition, under our Cell Line License Agreement, if we manufacture all of our commercial supplies of 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 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.

Our current and anticipated future dependence upon others for the manufacture of IMG-007 or any future product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

In the event that any of our manufacturers fails to comply with applicable requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of future global pandemics, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture IMG-007 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 IMG-007 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, if 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.

In addition, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We 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.

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 IMG-007 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 our IMG-007 or any future product candidates. We rely on CROs 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 CROs 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 CROs' 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 CROs does not relieve us of our regulatory responsibilities.

We and our CROs 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 CROs 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 CROs does not relieve us of our regulatory responsibilities. If we or our CROs 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 CROs 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 CROs 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 CROs 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 CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs 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 CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, we may encounter challenges or delays in the future and we cannot assure you 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007. 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with IMG-007 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 IMG-007 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 IMG-007 or any future product candidates; and
- collaborators may own or co-own intellectual property covering IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 for the treatment of moderate-to-severe AD. The key competitive factors affecting the success of IMG-007, if approved, are likely to be its safety and tolerability, efficacy, frequency of dosing, method of administration, convenience, price, and the availability of coverage and reimbursement from government and other third-party payors. There are several approved products for moderate-to-severe AD, such as DUPIXENT[®] (dupilumab), an IL-4R α mAb marketed by Sanofi/Regeneron, ADBRY[®] (tralokinumab-ldrm), an IL-13 mAb marketed by Leo Pharmaceuticals, and EBGLYSS[™] (lebrikizumab-lbkz), an IL-13 mAb marketed by Eli Lilly. There are several approved treatments that target JAK1 and/or JAK2 to treat AD, including CIBINQO[®] (abrocitinib) marketed by Pfizer, RINVOQ[®] (upadacitinib) by AbbVie, OLUMIANT[®] (baricitinib) marketed by Eli Lilly, and NEMLUVIO[®] (nemolizumab-ilto) marketed by Galderma Laboratories, L.P. These approved products have all demonstrated clinically significant efficacy results.

In addition, clinical stage monoclonal antibodies targeting OX-40 or OX40L for the AD indication include rocatinlimab, an antiOX40 receptor mAb with an enhanced antibody-dependent cellular cytotoxicity (“ADCC”) in development by Amgen, amlitelimab, an anti-OX40L mAb in development by Sanofi, STAR-0310, an anti-OX40 mAb by Astria Therapeutics, and APG990, an anti-OX40L mAb by Apogee Therapeutics. Rocatinlimab and amlitelimab are both ahead of IMG-007 in development. We are also aware of additional programs in development for AD which are focused largely on biologic approaches.

The enrollment and retention of patients in clinical trials for IMG-007 may be disrupted or delayed as a result of clinicians’ and patients’ perceptions as to the potential advantages of IMG-007 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, for the treatment of AD.

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 IMG-007 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 IMG-007 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 revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Coverage and reimbursement may be limited or unavailable in certain market segments for IMG-007 or any future product candidates, which could make it difficult for us to sell for IMG-007 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 IMG-007 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 IMG-007 or any future product candidates.

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. The EU provides options for EU Member States to 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. An EU Member State 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, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. 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 IMG-007 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 IMG-007 or any future product candidates that we may develop.

The use of IMG-007 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 and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our IMG-007 or any future product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- decreased demand for IMG-007 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 are 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 IMG-007 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.

IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 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. On April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, the date of which cannot currently be anticipated. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

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 IMG-007 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 IMG-007 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 EMA’s 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 EU, 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 IMG-007 or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of IMG-007 or any future product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of IMG-007 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, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of IMG-007 and any future product candidates will be harmed.

Even if we receive regulatory approval of IMG-007 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 IMG-007 or any future product candidates.

Any regulatory approvals that we receive for IMG-007 or any future product candidates will require surveillance to monitor the safety and efficacy of such product candidate. The FDA may also require a REMS in order to approve IMG-007 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 IMG-007 or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 may and our third-party manufacturers or suppliers and current or potential future collaborators will 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 IMG-007 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 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; state and local laws requiring the registration of pharmaceutical sales representatives; 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/or 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/or 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 IMG-007 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.

IMG-007 will be regulated as a biologic, and therefore they 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 of 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.

Even if we obtain regulatory approval of IMG-007 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 IMG-007 for the treatment of moderate-to-severe AD 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 IMG-007 or any future product candidates are accepted in the market include:

- the clinical indications for which IMG-007 or any future product candidates are approved;
- physicians, hospitals and patients considering IMG-007 or any future product candidates as a safe and effective treatment;
- the potential and perceived advantages of IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates, if approved. In particular, in 2010 the Affordable Care Act 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 IMG-007, 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. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute.

Since its enactment, there have been executive, judicial and political challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how other healthcare reform measures of the second Trump administration, if any, will impact our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on July 4, 2025, the annual reconciliation bill, the OBBBA, was signed into law which 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. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. In addition, 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. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, which was previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024. 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.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. For example, IRA, among other things, (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for 11 years covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law (the "Medicare Price Negotiation Program"), and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. For example, on September 30, 2025, the Trump administration announced the first agreement with a major pharmaceutical company that requires the drug manufacturer 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) reducing agency workforce and cutting programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (“CMMI”) to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration’s executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) 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; (5) imposing tariffs on imported pharmaceutical products; (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans; and (7) as part of the Make America Healthy Again (“MAHA”) Commission’s recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. 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. Additionally, in its June 2024 decision in *Loper Bright*, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. 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 created under the IRA.

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.

In the EU, similar developments may affect our ability to profitably commercialize IMG-007 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 IMG-007 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.

On December 13, 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and applies as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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

- the demand for IMG-007 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 CCPA applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses 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 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, 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 in the United States such as the Department of Justice 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 individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

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, 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; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

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 may be subject to new and emerging data privacy regimes in Asia, including China’s Personal Information Protection Law, 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”), also apply to our operations.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the 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 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, whitepapers, and other statements, concerning data privacy, and security. Regulators in the United States 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.

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/or 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/or 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 artificial intelligence 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 IMG-007 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 IMG-007. 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 IMG-007 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 IMG-007 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 IMG-007, we cannot be certain that the claims in Hutchmed’s pending patent applications directed to composition of matter of IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting IMG-007 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 IMG-007 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 IMG-007 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 13 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 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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, IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 and/or consulting agreements entered into by our officers, employees, independent contractors and/or 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 or any future product candidates. We may incorrectly determine that IMG-007 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 IMG-007 or any future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market IMG-007 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 IMG-007 or any future product candidates. We might, if possible, also be forced to redesign IMG-007 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 IMG-007 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. Non-compliance events that could result in abandonment or lapse 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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 IMG-007 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, IMG-007 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 IMG-007 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 IMG-007 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 IMG-007, may continue to do so in the future and expect to collaborate with third parties on the development of IMG-007 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 advisors 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 and/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 and/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 and/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, IMG-007 or any future product candidates may require the use of additional proprietary rights held by third parties. IMG-007 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 IMG-007 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, 2025, we had 15 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 IMG-007 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/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize IMG-007 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. We do not have formal employment agreements with certain of our executive officers and 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, a loss of customers or sales, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, 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, pre-clinical 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, 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, software bugs, hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence (“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 severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive information), loss of income, significant extra expenses to restore data or systems, reputational 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/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future 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, employee 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/or 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/or 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 cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation. 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 IMG-007 or any future product candidates could be delayed. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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 IMG-007 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 assure you 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 and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

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

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, 2024, we had U.S. federal net operating loss (“NOL”) carryforwards and state NOL carryforwards of \$192.8 million and \$214.6 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 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 IRA 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 IMG-007 and any future product candidates, and delays or failures to obtain such approvals;
- failure of IMG-007 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 IMG-007 or our future product candidates;
- any inability to obtain adequate supply of IMG-007 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 (our "Board") 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, 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, 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 our stockholders’ ability 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 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, the 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 our stockholders’ ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of 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 develop 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 never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

Effective as of the closing of the Merger, certain executive officers, directors and their affiliates, and greater than 5% stockholders of Legacy Inmagene and certain directors of Ikena that remained on our Board following the Closing, entered into lock-up agreements (the “Lock-Up Agreements”) pursuant to which, and subject to specified exceptions, they have agreed not to transfer this shares of our common stock until January 21, 2026, which is 180 days following the closing of the Merger. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, including upon the expiration or release of lock-up restrictions pursuant to the terms of the Lock-Up Agreements, the

trading price of our common stock could decline. We are not able to predict the effect that sales may have on the prevailing 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.

Imagene identified a material weakness in its 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 Imagene's financial statements for the years ended December 31, 2023 and 2024, a material weakness was identified in its 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.

Legacy Imagene 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 Legacy Imagene's 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 IMG-007 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, military conflict, including the conflict between Russia and Ukraine and the ongoing conflicts in the Middle East, 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, including the one in Ukraine, 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.

None.

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, 2025, 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).
4.2	Fourth Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated as of December 18, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-253919) filed with the SEC on March 5, 2021).
4.3	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).
10.1	The Registrant's 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-290108) filed with the SEC on September 8, 2025).
10.2	Forms of Option Award Notice, Option Agreement and Notice of Exercise under the Registrant's 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.21 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.3	Forms of Restricted Stock Unit Grant Notice and Unit Award Agreement under the Registrant's 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.4	The Registrant's 2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-290108) filed with the SEC on September 8, 2025).
10.5	The Registrant's 2025 Equity Inducement Plan and Forms of Stock Option Grant Notice, Option Agreement, and Notice of Exercise and Forms of RSU Grant Notice and RSU Agreement thereunder (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on August 1, 2025).
10.6	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-290108) filed with the SEC on September 8, 2025).
10.7	Contingent Value Rights Agreement by and between the Registrant and Computershare Trust Company, N.A., as rights agent, dated July 25, 2025 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.8	Contingent Value Rights Agreement by and among the Registrant, Legacy Inmagene and Computershare Trust Company, N.A., as rights agent, dated July 25, 2025 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.9	Transition Services Agreement by and between the Registrant and Miragene Inc, dated July 25, 2025 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.10	Offer Letter by and between the Registrant and Kristin Yarema, Ph.D., dated July 23, 2025 (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).
10.11	Amendment to Employment Agreement, dated July 15, 2025, by and between the Registrant and Jotin Marango, M.D., Ph.D. (incorporated by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q (File No. 001-40287) filed with the SEC on July 24, 2025).
10.12	Separation Agreement, dated July 23, 2025, by and between the Registrant and Jonathan Wang (incorporated by reference to Exhibit 10.18 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on July 29, 2025).

31.1*	Certification of Principal Executive Officer and 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.

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 12, 2025

By: /s/ Kristin Yarema
Kristin Yarema, PhD
Chief Executive Officer (Principal
Executive Officer and Interim Principal
Financial Officer)

Date: November 12, 2025

By: /s/ Erin Butler
Erin Butler
Senior Vice President, Finance and
Administration (Principal Accounting
Officer)

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.

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

**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, 2025 of ImagenBio, 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 his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2025

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