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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to _____

Commission file number 001-36177

Crescent Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Cayman Islands	**06-1686563**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
300 Fifth Avenue **Waltham, MA**	**02451**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 430-5595

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, $0.001 par value per share	CBIO	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of November 11, 2026, there were 38,895,442 of the issuer’s ordinary shares outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, are forward-looking statements, including, without limitation, statements regarding:

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the expected timing for initiation, trial design, and indication selection for our planned trials, and the timing and success of clinical data for our ongoing clinical trials;
- our ability to advance clinical development of, and ultimately obtain approval from, the U.S. Food and Drug Administration ("FDA") and other regulatory agencies in countries outside of the U.S. for our product candidates;
- our research and development plans and ability to identify and bring forward additional product candidates into preclinical and clinical development;
- the rate and degree of market acceptance of our product candidates, including our ability to successfully compete with existing therapies and therapies currently in development, and our expectations regarding the size of the commercial markets for our product candidates;
- our future marketing and sales programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates;
- our use of net proceeds from financing activities, including the availability of, and our ability to obtain, additional financing and to continue as a going concern;
- the effects of existing and future federal, state and foreign regulations and our expectations regarding the impact of macroeconomic conditions and geopolitical conflicts on our business and operations;
- the seeking and execution of joint development, licensing or distribution and collaboration and marketing arrangements with third parties;
- the timing and amount of milestone, royalty or other contingent consideration that we may receive or be required to pay under our license, collaboration and other agreements;
- the period of time for which our existing cash and cash equivalents will enable us to fund our operations; and
- our relationship with Paragon Therapeutics, Inc., Fairmount Funds Management LLC, and Parascent Holding LLC.

Forward-looking statements generally relate to future events or our future financial or operating performance. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that may cause actual results to differ materially from current expectations include the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, our development activities and those other factors we discuss in "Summary Risk Factors," Part II, Item 1A. "Risk Factors," and Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q ("Form 10-Q"). You should read these risk factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. The risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance.

Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Preliminary and interim or initial results from any trial and results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

As used in this Quarterly Report, unless the context suggests otherwise, “we,” “us,” “our,” “the Company,” “Crescent Biopharma, Inc.,” “Crescent,” “GlycoMimetics, Inc.,” “GlycoMimetics,” refers to Crescent Biopharma, Inc. and its consolidated subsidiaries, including Crescent Biopharma Operating Company LLC, taken as a whole.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. The principal risks and uncertainties affecting our business include the following:

Risks Related to Our Financial Condition and Capital Requirements

- We are a clinical-stage biotechnology company with a limited operating history on which to assess our business; we have not completed any clinical trials, and have no products approved for commercial sale.
- We have historically incurred losses and we anticipate that we will continue to incur losses for the foreseeable future.
- We have never generated revenue from product sales and may never be profitable.
- We may not be able to raise the capital that we need to support our business plans.
- Raising additional capital may cause additional dilution to our shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

Risks Related to Clinical Development and Regulatory Approval

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- We are substantially dependent on the success of our lead program, CR-001, and our current and anticipated clinical trials of such program may not be successful.
- We may not be able to meet requirements for the chemistry, manufacturing, and control of our programs.
- We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.
- The FDA and comparable foreign regulatory approval processes are lengthy and time consuming and we may not be able to obtain or may be delayed in obtaining regulatory approvals for our product candidates.
- Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.
- Even if we obtain regulatory approval, we will be subject to ongoing regulatory obligations.
- We may fail to achieve our projected development goals in the time frames we announce and expect.

Risks Related to Our Intellectual Property

- We do not currently solely own any issued patents or pending patent applications and our patent portfolio is in-licensed from Paragon Therapeutics, Inc. ("Paragon") and Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. ("Kelun").
- Our ability to obtain and protect patent rights and protect other proprietary rights is uncertain.
- We may fail in obtaining or maintaining necessary rights to our programs.
- We may be subject to patent infringement claims or may need to file such claims.
- Our ability to protect our products may be impaired by changes to patent laws.
- Our patent protection could be reduced or eliminated for non-compliance with legal requirements.
- We may fail to identify or interpret relevant third-party patents.
- We may become subject to claims challenging the inventorship or ownership of our intellectual property.
- Patent terms may be inadequate to protect the competitive position of our programs.

- Our technology licensed from Paragon and Kelun and any technology licensed from other third parties in the future may be subject to retained rights.
- We may be unable to protect the confidentiality of our trade secrets and other proprietary information.
- We may become subject to litigation under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") in connection with patent rights for our product candidates.

Risks Related to Our Reliance on Third Parties

- We currently and in the future expect to rely on agreements with third parties to develop our product candidates. If we are unable to maintain our current or future collaborations or licensing arrangements, or if our current or future collaborations or licensing arrangements are not successful, our business could be negatively impacted. Additionally, in some instances, our agreements with third parties may include certain indemnification provisions which, if triggered, may negatively impact our business.
- Third parties we rely on for the execution of nonclinical studies and clinical trials may fail to carry out their contractual duties.
- We may be unable to use third-party manufacturing sites, our third-party manufacturers may encounter difficulties in production, or we may need to switch or create third-party manufacturer redundancies.

Other Risk Factors - Risks Related to Employee Matters, Managing Growth, Other Risks Related to Our Business, and Owning Our Ordinary Shares

- Our business is dependent on key personnel and we will be harmed if we cannot recruit and retain highly qualified personnel to successfully implement our business strategy.
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.
- Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations, and standards may adversely affect our business, operations, and consolidated financial performance.
- We may become exposed to costly and damaging liability claims and our insurance may not cover all damages from such claims.
- Our business could be adversely affected by macroeconomic conditions, including tariffs.
- We do not anticipate paying any dividends in the foreseeable future.
- Future sales of shares by existing shareholders, including any shares issuable upon exercise of any pre-funded warrants, could cause our share price to decline.
- Future sales and issuances of equity and debt could result in additional dilution to our shareholders and could cause our share price to decline.

Part I. Financial Information

Item 1. Financial Statements

CRESCENT BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 289,357	$ 213,192
Accounts receivable, net	—	18,000
Prepaid expenses and other current assets	5,854	5,463
Total current assets	295,211	236,655
Property and equipment, net	809	846
Operating lease right-of-use assets	2,280	1,469
Restricted cash	219	107
Other assets	984	1,216
Total assets	$ 299,503	$ 240,293
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 1,620	$ 9,997
Accrued expenses and other current liabilities	21,146	16,344
Related party accounts payable and other current liabilities	—	140
Deposit liability	—	5,000
Deferred revenue	—	4,156
Operating lease liability, current	724	435
Total current liabilities	23,490	36,072
Long term liabilities		
Operating lease liability, noncurrent	1,734	1,209
Total liabilities	25,224	37,281
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Non-voting convertible preferred shares, $0.001 par value; 5,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 2,890 Series A preferred shares issued and outstanding as of September 30, 2026 and December 31, 2025	4,000	4,000
Ordinary shares, $0.001 par value; 175,000,000 shares authorized as of September 30, 2026 and December 31, 2025, 38,181,157 and 27,556,767 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	38	28
Additional paid-in capital	527,896	370,793
Accumulated deficit	(257,655)	(171,809)
Total shareholders' equity	274,279	203,012
Total liabilities and shareholders' equity	$ 299,503	$ 240,293

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

CRESCENT BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(in thousands, except share and per share amounts)

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
License agreement revenue	$ 3,117	$ 4,156	$ —	$ —
Operating expenses				
Research and development[1]	34,305	71,598	20,347	43,059
General and administrative[2]	8,719	25,328	5,538	18,081
Total operating expenses	43,024	96,926	25,885	61,140
Other operating income	—	1,770	—	—
Loss from operations	(39,907)	(91,000)	(25,885)	(61,140)
Other income (expense):				
Interest income	2,181	5,154	1,278	1,780
Interest expense[3]	—	—	—	(2,185)
Total other income (expense)	2,181	5,154	1,278	(405)
Net loss and comprehensive loss	$ (37,726)	$ (85,846)	$ (24,607)	$ (61,545)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.90)	$ (2.37)	$ (1.27)	$ (7.89)
Net loss per share attributable to Series A non-voting convertible preferred shareholders, basic and diluted	$ (899.31)	$ (2,368.17)	$ (1,266.44)	$ (7,891.38)
Weighted-average ordinary shares outstanding used in computing net loss per share to ordinary shareholders, basic and diluted	39,056,224	33,360,473	16,540,771	6,640,402
Weighted-average Series A non-voting convertible preferred shares outstanding used in computing net loss per share to Series A non-voting convertible preferred shareholders, basic and diluted	2,890	2,890	2,890	1,160

(1) Includes related party amount of $3,000 and $5,923 for the three and nine months ended September 30, 2026, respectively, and $6,175 and $21,244 for the three and nine months ended September 30, 2025, respectively.

(2) There were no related party amounts for the three and nine months ended September 30, 2026 and $89 and $719 for the three and nine months ended September 30, 2025, respectively.

(3) There were no related party amounts for the three and nine months ended September 30, 2026 and $0 and $865 for the three and nine months ended September 30, 2025, respectively.

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

CRESCENT BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)
(In thousands, except share amounts)

	Convertible Preferred Stock		Non-Voting Preferred Shares		Ordinary Shares[1]		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances as of December 31, 2024	20,000,000	$ 4,000	—	$ —	1,018,604	$ 1	$ 2,387	$ (17,867)	$ (15,479)
Share-based compensation expense	—	—	—	—	—	—	466	—	466
Early exercise of stock options	—	—	—	—	811	—	—	—	—
Net loss	—	—	—	—	—	—	—	(15,148)	(15,148)
Balances as of March 31, 2025	20,000,000	$ 4,000	—	$ —	1,019,415	$ 1	$ 2,853	$ (33,015)	$ (30,161)
Repurchase and cancellation of restricted stock awards	—	—	—	—	(127,889)	—	(177)	—	(177)
Exchange of Series Seed convertible preferred stock for Series A designated non-voting convertible preferred shares upon the closing of the reverse recapitalization	(20,000,000)	(4,000)	2,890	4,000	—	—	—	—	4,000
Conversion of convertible notes (including accrued interest) into ordinary shares and pre-funded warrants upon the closing of the reverse recapitalization	—	—	—	—	1,850,790	2	40,513	—	40,515
Issuance of ordinary shares and pre-funded warrants in the Pre-Closing financing	—	—	—	—	10,504,926	11	159,464	—	159,475
Issuance costs of Pre-closing financing and reverse recapitalization	—	—	—	—	—	—	(17,201)	—	(17,201)
Issuance of ordinary shares to former shareholders of GLYC in connection with the closing of the reverse recapitalization	—	—	—	—	645,274	—	525	—	525
Share-based compensation expense	—	—	—	—	—	—	4,068	—	4,068
Net loss	—	—	—	—	—	—	—	(21,790)	(21,790)
Balances as of June 30, 2025	—	$ —	2,890	$ 4,000	13,892,516	$ 14	$ 190,045	$ (54,805)	$ 139,254
Share-based compensation expense	—	—	—	—	—	—	1,994	—	1,994
Net loss	—	—	—	—	—	—	—	(24,607)	(24,607)
Balances as of September 30, 2025	—	$ —	2,890	$ 4,000	13,892,516	$ 14	$ 192,039	$ (79,412)	$ 116,641

(1) Includes 168,215 restricted stock awards outstanding as of September 30, 2025.

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

CRESCENT BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)
(In thousands, except share amounts)

	Convertible Preferred Stock		Non-Voting Preferred Shares		Ordinary Shares[1]		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances as of December 31, 2025	—	$ —	2,890	$ 4,000	27,556,767	$ 28	$ 370,793	$ (171,809)	$ 203,012
Issuance of Parascent warrants	—	—	—	—	—	—	423	—	423
Release of restricted stock units	—	—	—	—	15,168	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	5	—	5
Share-based compensation expense	—	—	—	—	—	—	3,690	—	3,690
Net loss	—	—	—	—	—	—	—	(23,283)	(23,283)
Balances as of March 31, 2026	—	$ —	2,890	$ 4,000	27,571,935	$ 28	$ 374,911	$ (195,092)	$ 183,847
Release of restricted stock units	—	—	—	—	158,937	—	—	—	—
Issuance of ordinary shares under employee stock purchase plan	—	—	—	—	25,172	—	280	—	280
Share-based compensation expense	—	—	—	—	—	—	3,965	—	3,965
Net loss	—	—	—	—	—	—	—	(24,837)	(24,837)
Balances as of June 30, 2026	—	$ —	2,890	$ 4,000	27,756,044	$ 28	$ 379,156	$ (219,929)	$ 163,255
Release of restricted stock units	—	—	—	—	45,965	—	—	—	—
Issuance of ordinary shares and warrants in July 2026 Offering, net of offering costs	—	—	—	—	9,387,896	9	133,422	—	133,431
Issuance of ordinary shares under the at-the-market ("ATM") offering program, net of commissions	—	—	—	—	545,524	1	11,009	—	11,010
Issuance of ordinary shares upon exercise of pre-funded warrants	—	—	—	—	437,554	—	—	—	—
Issuance of ordinary shares upon exercise of stock options	—	—	—	—	8,174	—	89	—	89
Share-based compensation expense	—	—	—	—	-	—	4,220	—	4,220
Net loss	—	—	—	—	-	—	—	(37,726)	(37,726)
Balances as of September 30, 2026	—	$ —	2,890	$ 4,000	38,181,157	$ 38	$ 527,896	$ (257,655)	$ 274,279

(1) Includes 168,215 restricted stock awards outstanding as of September 30, 2026.

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

CRESCENT BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Cash flows from operating activities:		
Net loss	$ (85,846)	$ (61,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense[1]	12,298	8,555
Gain on sale of assets	(1,770)	—
Depreciation expense	197	30
Non-cash interest expense[2]	—	2,185
Non-cash lease expense	314	117
Changes in operating assets and liabilities:		
Accounts payable	(2,022)	1,057
Accrued expenses and other current liabilities	13,257	6,422
Related party accounts payable and other current liabilities	(140)	(948)
Deposit liability	(5,000)	—
Deferred revenue	(4,156)	—
Operating lease liability	(311)	60
Accounts receivable	18,000	—
Prepaid expenses and other current assets	(391)	(850)
Other assets	233	125
Net cash used in operating activities	(55,337)	(44,792)
Cash flows from investing activities:		
Purchase of research and development license	(8,000)	—
Proceeds received from sale of assets	1,770	—
Purchases of property and equipment	(160)	(726)
Net cash used in investing activities	(6,390)	(726)
Cash flows from financing activities:		
Proceeds from at-the-market offering, net of commissions	11,125	—
Proceeds from exercise of employee stock options	89	—
Proceeds from the July 2026 offering	135,124	—
Proceeds from the Pre-Closing Financing, net	—	143,027
Cash acquired in connection with the reverse recapitalization	—	1,269
Proceeds from early exercise of options	—	5
Repurchase of equity awards	—	(177)
Payment of deferred offering costs	(8,614)	—
Proceeds from issuance of shares under employee stock purchase plan	280	—
Net cash provided by financing activities	138,004	144,124
Net increase in cash, cash equivalents, and restricted cash	76,277	98,606
Cash, cash equivalents, and restricted cash at beginning of period	213,299	34,766
Cash, cash equivalents, and restricted cash at end of period	$ 289,576	$ 133,372
Supplemental disclosure of non-cash operating and financing activities:		
Vesting of early exercised stock options	$ 5	$ —
Deferred financing costs included in accounts payable and accrued expenses and other current liabilities	$ 140	$ 19
Operating lease liability arising from obtaining operating right-of-use asset	$ 1,125	$ 1,681
Assets acquired in connection with the reverse recapitalization	$ —	$ 1,710
Other liabilities assumed in connection with the reverse recapitalization	$ —	$ (2,454)
Purchases of property and equipment included in accounts payable and accrued expenses and other current liabilities	$ —	$ 86
Convertible note principal and non-cash accrued interest converted to ordinary shares	$ —	$ 40,515

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

Non-cash exchange of Pre-Merger Crescent Series Seed Preferred Stock for Series A Non-Voting Convertible Preferred Shares	$	—	$	4,000

(1) Includes related party amount of $423 and $2,027, for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $865 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

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

CRESCENT BIOPHARMA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business

Background

Crescent Biopharma, Inc., together with its subsidiaries (collectively "Crescent" or the "Company"), formerly known as GlycoMimetics, Inc. ("GlycoMimetics"), is a clinical-stage biotechnology company that is the result of the reverse recapitalization discussed below. Prior to the reverse recapitalization, the private company Crescent Biopharma, Inc. ("Pre-Merger Crescent") was established and incorporated under the laws of the state of Delaware on September 19, 2024. The Company was founded to research and develop cancer therapy candidates licensed from Paragon Therapeutics, Inc. ("Paragon"), an antibody discovery engine founded by Fairmount Funds Management LLC ("Fairmount"). The Company is based in Waltham, Massachusetts and was formed to develop therapies for the treatment of solid tumors.

These condensed consolidated financial statements reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of September 30, 2026, its results of operations for the three and nine months ended September 30, 2026 and 2025, and its cash flows for the nine months ended September 30, 2026 and 2025. The condensed balance sheet as of December 31, 2025, included in the condensed consolidated balance sheets was derived from the Company's audited financial statements. The condensed consolidated financial statements and accompanying notes are prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for interim financial reporting and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and therefore do not include all information and disclosures normally included in the annual financial statements. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 26, 2026. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results expected for the full fiscal year or any subsequent interim period. The condensed consolidated financial statements include the financial statements of its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Reverse Recapitalization, Pre-Closing Financing, and Reverse Stock Split

On June 13, 2025, the Company consummated the closing (the "Closing") pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of October 28, 2024, which agreement was subsequently amended on February 14, 2025 and April 28, 2025 (as amended, the "Merger Agreement"). Immediately prior to the consummation of the Merger, GlycoMimetics effected a 1-for-100 reverse stock split of GlycoMimetics common stock, which became legally effective on June 13, 2025 (the "Reverse Stock Split"). The Company's common stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the open of trading on June 16, 2025. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock 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 Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

We are led by the Pre-Merger Crescent management team and remain focused on developing differentiated oncology therapeutics for patients living with solid tumors. The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Crescent was deemed to be the accounting acquirer for financial reporting purposes.

In connection with the Merger, Pre-Merger Crescent and GlycoMimetics entered into an amended and restated subscription agreement (the "Subscription Agreement") with certain new and existing investors of Pre-Merger Crescent (the "Financing Investors"), pursuant to which such investors purchased, immediately prior to the first merger, 85,506,824 shares of Pre-Merger Crescent common stock and 19,149,690 Pre-Merger Crescent pre-funded warrants, for gross proceeds of approximately $200.0 million (which includes $37.5 million of proceeds previously received from the issuance of convertible notes and $3.0 million of accrued interest thereon) (the "Pre-Closing Financing"). Under the Subscription Agreement, the number of shares of Pre-Merger Crescent common stock or Pre-Merger Crescent pre-funded warrants were converted into 12,355,716 shares of Company common stock and 2,767,122 pre-funded warrants of Company common stock in accordance with the Exchange Ratio (defined below).

The Exchange Ratio was calculated using a formula intended to allocate existing GlycoMimetics and Pre-Merger Crescent security holders a percentage of the Company. Based on GlycoMimetics' and Pre-Merger Crescent's values as of the date of the Merger Agreement and capitalization as of June 13, 2025, the Exchange Ratio (as adjusted for the Reverse Stock Split) was 0.1445 shares of GlycoMimetics common stock for each share of Crescent common stock.

Redomestication

On June 16, 2025, Crescent changed its jurisdiction of incorporation from the State of Delaware to the Cayman Islands (the "Redomestication") pursuant to a plan of conversion. The Redomestication became effective on June 16, 2025 and was accomplished by the filing of (i) a Certificate of Conversion with the Secretary of State of the State of Delaware and (ii) the requisite documents required under section 201 of the Companies Act (as amended) of the Cayman Islands (the "Companies Act"), as well as the Company's memorandum and articles of association (the "Articles"), with the Cayman Islands Registrar of Companies. For purposes of these condensed consolidated financial statements, references to "Crescent Delaware" mean Crescent prior to the Redomestication.

Upon the Redomestication, among other things: (i) each outstanding share of common stock, par value $0.001 per share, of Crescent Delaware automatically converted into one ordinary share, par value $0.001 per share, of the Company; (ii) each outstanding share of Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share, of Crescent Delaware automatically converted into one share of Series A Non-Voting Convertible Preferred Share, par value $0.001 per share, of the Company (the "Series A Preferred Shares"); (iii) each outstanding option to purchase shares of common stock of Crescent Delaware automatically converted into an option to purchase ordinary shares of the Company; (iv) each outstanding restricted stock unit of Crescent Delaware automatically converted into a restricted stock unit of the Company; and (v) each warrant to purchase shares of common stock of Crescent Delaware automatically converted into a warrant to purchase ordinary shares of the Company.

The rights of holders of ordinary shares of the Company are now governed by the Articles and Cayman Islands law.

Liquidity

Since its 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 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 and debt financings.

The Company has incurred significant operating losses and negative cash flows from operations since inception. During the three and nine months ended September 30, 2026, the Company incurred a net loss of $37.7 million and $85.8 million, respectively. During the nine months ended September 30, 2026, the Company used net cash of $55.3 million for its operating activities. The Company has an accumulated deficit of $257.7 million at September 30, 2026.

As of September 30, 2026, the Company had cash and cash equivalents of $289.4 million. The Company's management expects that the existing cash will be sufficient to fund the Company's operating plans for at least twelve months from the date these condensed consolidated financial statements were issued. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting future preclinical activities and clinical trials and manufacturing for its existing product candidates and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay, or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations, or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition, and results of operations.

2. Basis of Presentation and Summary of Significant Accounting Policies

Significant accounting policies

The Company's significant accounting policies are disclosed in its Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC and have not materially changed during the nine months ended September 30, 2026.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected within these financial statements include but are not limited to research and development expenses and any applicable prepaid or accrued costs and the valuation of share-based compensation awards and related expenses. The Company bases its estimates on known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts, and experience. Actual results may differ materially from those estimates or assumptions.

Research and Development Contract Costs Accruals

The Company records the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's ongoing research and development activities conducted to date by vendors, including the Company's related party Paragon (see Note 11), contract manufacturing organizations ("CMOs"), and contract research organizations ("CROs").

The Company accrues for expenses resulting from obligations under its discovery and option agreements by and among the Company, Paragon and Parascent Holding LLC ("Parascent"), and agreements with CROs, CMOs, and other vendors for which payment flows may not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with Paragon, CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to Paragon, a CRO, CMO, or other outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. As of September 30, 2026, the Company has not experienced any material deviations between accrued and actual research and development expenses.

Commitments and Contingencies

The Company may be subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the condensed consolidated balance sheet. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of September 30, 2026, no liabilities were recorded for loss contingencies (see Note 13).

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for the Company's annual reporting period beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements ("ASU 2025-11"). The amendments in ASU 2025-11 clarify interim disclosure requirements. ASU 2025-11 is effective for the Company's annual reporting period beginning after December 15, 2027 and interim reporting periods beginning after December 15, 2028, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements.

3. Fair Value of Financial Instruments

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets carried at fair value categorized using the lowest level of input applicable to each financial instrument as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 157,684	$ —	$ —	$ 157,684
Total Assets	$ 157,684	$ —	$ —	$ 157,684

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 124,522	$ —	$ —	$ 124,522
Total Assets	$ 124,522	$ —	$ —	$ 124,522

Cash equivalents consist of money market funds, which were valued by the Company based on quoted market prices, which represents a Level 1 measurement within the fair value hierarchy. The Company did not hold any financial liabilities carried at fair value as of September 30, 2026 and December 31, 2025.

Prior to the termination of the ADC Paragon Option Agreement (as defined below) on March 26, 2026, the Company re-measured the warrant liability each reporting period and recorded changes in the fair value through research and development expenses on the Company's consolidated statements of operations (as discussed further in Note 9). Upon termination, the warrants are equity classified and are no longer subject to remeasurement at fair value. The following table shows the changes in fair value measurements using significant unobservable inputs (Level 3) for the warrant liability during the three and nine months ended September 30, 2026 and September 30, 2025:

Description	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
Beginning balance	$ —	$ —	$ 2,096	$ 61
Change in fair value	—	423	(8)	2,027
Issuance of warrant	—	(423)	—	—
Ending balance	$ —	$ —	$ 2,088	$ 2,088

4. Restricted Cash

Restricted cash as of September 30, 2026 and September 30, 2025 was held as collateral for a stand-by letter of credit issued by the Company in connection with the current leases for its principal facilities. For additional information regarding the Company's lease, refer to Note 12. Cash, cash equivalents, and restricted cash consisted of the following as of September 30, 2026 and September 30, 2025 (in thousands):

	September 30, 2026	September 30, 2025
Cash and cash equivalents	$ 289,357	$ 133,265
Restricted cash	219	107
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 289,576	$ 133,372

5. Prepaid Expenses and Other Current Assets

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

	September 30, 2026	December 31, 2025
Prepaid research and development services	$ 4,032	$ 4,185
Other prepaid expenses and other current assets	1,822	1,278
Total prepaid expenses and other current assets	$ 5,854	$ 5,463

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2026	December 31, 2025
Accrued withholding taxes	$ —	$ 8,000
Accrued research and development	14,617	2,424
Accrued professional and consulting	1,079	799
Accrued employee compensation and benefits	5,450	5,121
Total accrued expenses and other current liabilities	$ 21,146	$ 16,344

7. Convertible Notes Payable

In October 2024, the Company entered into a Convertible Note Purchase Agreement (the "Note Purchase Agreement") with a series of investors, pursuant to which the Company issued convertible notes with an initial principal amount of $37.5 million (of which $15.0 million was from a related party) (the "Convertible Notes"). The principal amount and all accrued interest of the Convertible Notes would automatically convert into the Pre-Merger Crescent's common stock or preferred stock in connection with the closing of a Next Equity Financing (as defined in the Note Purchase Agreement) or other events (e.g., a sale of substantially all Company assets, a merger, etc.). The Convertible Notes accrued interest at a rate of 12.0% per annum, compounded annually. All unpaid interest and principal was scheduled to mature on December 31, 2026 (the "Maturity Date"). Prepayment was not permitted without the prior written consent of the majority of the holders of the Convertible Notes. The principal payment along with the accrued interest on each Convertible Note was due in full on the Maturity Date. Pursuant to the Note Purchase Agreement, the Company had the right to sell and issue additional Convertible Notes up to an aggregate principal amount equal to $37.5 million, in addition to the $37.5 million of initial principal amount of the Convertible Notes for a total aggregate principal amount of up to $75.0 million.

The Company assessed all terms and features of the Convertible Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the embedded features. The Company determined that the share settled redemption feature was clearly and closely related to the debt host and did not require separate accounting. The Company determined that the conversion options of the Convertible Notes, including the conversion features related to a defaulting purchaser and highest interest rate, were not clearly and closely associated with a debt host. However, these features did not meet the definition of a derivative under ASC 815, Derivatives and Hedging, and as a result, did not require separate accounting as a derivative liability.

The Company paid debt issuance costs of less than $0.1 million in relation to the Convertible Notes. The debt issuance costs were reflected as a reduction of the carrying value of Convertible Notes on the condensed consolidated balance sheet and were amortized as interest expense over the term of the Convertible Notes using the effective interest method. For the three months ended September 30, 2025, the Company recognized no interest expense related to the Convertible Notes. For the nine months ended September 30, 2025, the Company recognized interest expense related to the Convertible Notes of $2.2 million, which includes non-cash interest expense related to the amortization of debt issuance. No interest expense

was recognized for the three and nine months ended September 30, 2026 due to the conversion of the Convertible Notes immediately prior to the closing of the Merger.

Immediately prior to the closing of the Merger, the Convertible Notes were converted into 12,808,261 shares of Pre-Merger Crescent common stock and pre-funded warrants to purchase 8,392,303 shares of Pre-Merger Crescent common stock based on the aggregate principal amount of $37.5 million plus $3.0 million in unpaid accrued interest divided by the conversion price in connection with the Pre-Closing Financing. At the closing of the Merger, the Pre-Merger Crescent common stock and pre-funded warrants issued in exchange for the Convertible Notes were converted into the right to receive 1,850,790 shares of common stock and pre-funded warrants to purchase 1,212,683 shares of common stock of the Company. In connection with the Redomestication, such shares of common stock and pre-funded warrants were converted to 1,850,790 ordinary shares and pre-funded warrants to purchase 1,212,683 ordinary shares of the Company, respectively. As of September 30, 2026, the Convertible Notes were not outstanding.

8. Convertible Preferred Shares and Shareholders' Equity (Deficit)

Pre-Funded Warrants

In June 2025, pursuant to the Subscription Agreement and immediately prior to the Closing, certain new and current investors purchased pre-funded warrants of Pre-Merger Crescent for $1.9109 per warrant prior to the Exchange Ratio, or $13.22 per warrant as adjusted for the Exchange Ratio. At the Closing of the Merger, pre-funded warrants of Pre-Merger Crescent automatically converted to pre-funded warrants of the Company to purchase 2,767,122 shares of the Company common stock at an exercise price of $0.001 per share. In connection with the Redomestication, such pre-funded warrants converted to pre-funded warrants to purchase 2,767,122 ordinary shares at an exercise price of $0.001 per share.

In December 2025, the Company entered into a securities purchase agreement for a private placement (the “Private Placement”), where certain institutional and other accredited investors purchased pre-funded warrants at a purchase price of $13.409 per share allowing for the purchase of 131,434 shares at an exercise price of $0.001 per share.

In July 2026, as part of the July 2026 Offering (defined below), certain current investors purchased pre-funded warrants at a purchase price of $14.499 per share allowing for the purchase of 525,897 shares at an exercise price of $0.001 per share.

All outstanding pre-funded warrants are exercisable immediately. A holder of a pre-funded warrant may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of ordinary shares outstanding immediately after giving effect to such exercise. Holders may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days’ prior notice to us. The pre-funded warrants were recorded as a component of shareholders’ equity within additional paid-in-capital and have no expiration date. As of September 30, 2026, 437,581 of the pre-funded warrants have been exercised through a cashless exercise into 437,554 of the Company’s ordinary shares.

Convertible Preferred Shares

In September 2024, Pre-Merger Crescent issued and sold 20,000,000 shares of the Series Seed Convertible Preferred Stock to a related party, Fairmount Healthcare Fund II L.P., an affiliate fund of Fairmount, at a purchase price of $0.20 per share for gross proceeds of $4.0 million.

Upon the issuance of the Pre-Merger Crescent Series Seed Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities as described below and determined that such features did not require the Company to separately account for these features as embedded derivatives.

In June 2025, upon the closing of the Merger, the outstanding Pre-Merger Crescent Series Seed Preferred Stock converted into 2,890 shares of Preferred Stock designated as Series A. In connection with the Redomestication, such shares of Series A designated Preferred Stock converted to 2,890 Series A Preferred Shares.

As of September 30, 2026 and December 31, 2025, Convertible Preferred Shares consisted of the following (in thousands, except share amounts):

	September 30, 2026				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding[1]	Carrying Value	Liquidation Preference	Ordinary Shares Issuable Upon Conversion
Preferred Shares	5,000,000	2,890	$ 4,000	$ —	2,890,000

	December 31, 2025				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding[1]	Carrying Value	Liquidation Preference	Ordinary Shares Issuable Upon Conversion
Preferred Shares	5,000,000	2,890	$ 4,000	$ —	2,890,000

(1) Preferred shares designated as Series A

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Shares (the "Series A Certificate of Designation"), holders of Series A Preferred Shares are entitled to receive dividends on shares of Series A Preferred Shares equal to, on an as-if-converted-to-Company ordinary shares basis, and in the same form as, dividends actually paid on Company ordinary shares. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Series A Preferred Shares do not have voting rights. The Series A Preferred Shares shall rank on parity with the Company ordinary shares as to the distribution of assets upon any liquidation, dissolution, or winding-up of the Company. Each Series A Preferred Share is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder into ordinary shares of the Company. As of September 30, 2026, each outstanding Series A Preferred Share was convertible into ordinary shares at a ratio of 1,000:1.

Ordinary Shares

As of September 30, 2026, the Company has the authority to issue a total of 175,000,000 ordinary shares at a par value of $0.001 per share. As of September 30, 2026, 38,181,157 ordinary shares were issued and outstanding, which includes 168,215 ordinary shares in connection with the issuance of RSAs. Each ordinary share entitles the holder to one vote, together with the holders of Convertible Preferred Shares, on all matters submitted to the shareholders for a vote. The holders of ordinary shares are entitled to receive dividends, if any, as declared by the Company's board of directors (the "Board of Directors" or "Board"), subject to the preferential dividend rights of the holders of Convertible Preferred Shares.

As of September 30, 2026, there were an aggregate of 16,745,027 ordinary shares reserved for issuance (i) for the conversion of Series A Preferred Shares into ordinary shares, (ii) for the exercise of outstanding and issued options for ordinary shares, (iii) for shares available for future grants, (iv) for settlement of outstanding RSUs for ordinary shares, (v) for the exercise of the pre-funded warrants, and (vi) for the exercise of the Parascent warrants.

ATM Program

On July 1, 2026, the Company entered into an open market sale agreement with Jefferies LLC, as sales agent, pursuant to which the Company may offer and sell from time to time up to an aggregate of $200.0 million of the Company's ordinary shares through an "at-the-market" equity offering program (the "ATM Program"). During the three and nine months ended September 30, 2026, the Company issued and sold an aggregate of 545,524 ordinary shares under the ATM Program for total net proceeds of $11.1 million, after deducting sales agent commissions. As of September 30, 2026, $188.5 million remained available under the ATM program.

Equity Offering

In July 2026, the Company entered into an underwriting agreement with Jefferies LLC, TD Securities (USA) LLC, Guggenheim Securities, LLC, Cantor Fitzgerald & Co, and LifeSci Capital LLC, as representatives of the several underwriters, relating to an underwritten public offering (the "July 2026 Offering") for the issuance and sale of 8,094,793 ordinary shares and 525,897 pre-funded warrants to purchase ordinary shares. The Company also granted the underwriters

an option to purchase up to 1,293,103 ordinary shares, which the underwriters exercised in full. The offering price to the public was $14.50 per ordinary share and $14.499 per warrant, for total net proceeds of $133.4 million after deducting underwriting discounts and commissions and related issuance expenses of $10.3 million.

9. Share-Based Compensation

2024 Equity Incentive Plan

The Crescent Biopharma, Inc. 2024 Equity Incentive Plan ("2024 Plan") was adopted by the board of directors of Pre-Merger Crescent on September 19, 2024. The 2024 Plan provided for Pre-Merger Crescent to grant stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, officers, directors, consultants, and advisors. Equity incentive stock options granted under the 2024 Plan generally vest over four years, subject to the participant's continued service, and expire after ten years, although stock options have been granted with vesting terms less than four years. As of September 30, 2026, there were no ordinary shares available for issuance under the 2024 Plan.

2025 Stock Incentive Plan

The Crescent Biopharma, Inc. 2025 Stock Incentive Plan (as amended from time to time, the "2025 Stock Plan") was approved by the board of directors of GlycoMimetics on May 11, 2025, and by GlycoMimetics stockholders on June 5, 2025, and effective as of the Redomestication, the Board of Directors approved an amendment and restatement of the 2025 Stock Plan to reflect the conversion of Company common stock into Company ordinary shares in connection with the Redomestication. The 2025 Stock Plan allows for the grant of stock options, stock appreciation rights, RSAs, RSUs, other shareholder-based awards and incentive bonuses. The 2025 Stock Plan is administered by the Compensation Committee of the Board (the "Compensation Committee") or another committee designated by the Board to administer the Plan. The initial share pool under the 2025 Stock Plan was 2,345,962 ordinary shares, and as of September 30, 2026, there are 1,775,895 shares available in the pool. The shares that may be issued under the 2025 Stock Plan are automatically increased on January 1 of each year beginning in 2026 and ending with a final increase on January 1, 2035 in an amount equal to 5% of the diluted shares (including ordinary shares, preferred shares and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. On January 1, 2026, 1,667,266 shares were added to the issuable shares under the 2025 Stock Plan. Current or prospective employees, officers, non-employee directors, and other independent service providers of the Company and its subsidiaries are eligible to participate in the 2025 Stock Plan.

2025 Employment Inducement Incentive Award Plan

The Crescent Biopharma, Inc. 2025 Employment Inducement Incentive Award Plan (as amended from time to time, the "2025 Inducement Plan") was approved by the board of directors of Crescent Biopharma, Inc. on October 30, 2025. The 2025 Inducement Plan allows for the grant of stock options, stock appreciation rights, RSAs, RSUs, other shareholder-based awards and incentive bonuses. The 2025 Inducement Plan is administered by the Compensation Committee or another committee designated by the Board to administer the Plan. The initial share pool under the 2025 Inducement Plan was 1,250,000 ordinary shares and was subsequently increased to 2,000,000 ordinary shares in September 2026. As of September 30, 2026, there are 889,449 shares available for future awards under the 2025 Inducement Plan.

2025 Employee Stock Purchase Plan

The Crescent Biopharma, Inc. 2025 Employee Stock Purchase Plan (as amended from time to time, the "ESPP") was approved by the board of directors of GlycoMimetics on May 11, 2025, and by GlycoMimetics stockholders on June 5, 2025, and effective as of the Redomestication, the Board of Directors approved an amendment and restatement of the ESPP to reflect the conversion of Company common stock into Company ordinary shares in connection with the Redomestication. The shares that may be issued under the ESPP are automatically increased on January 1 of each year beginning in 2026 and ending with a final increase on January 1, 2035 in an amount equal to 1% of the diluted shares (including ordinary shares, preferred shares and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. On January 1, 2026, 333,453 shares were added to the issuable shares under the ESPP. As of September 30, 2026, 25,172 shares have been issued out of the ESPP and 503,778 shares remain reserved for issuance.

Stock Option Valuation

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards during the nine months ended September 30, 2026 and September 30, 2025:

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Expected term (in years)	6.0	6.1
Expected volatility	107.6%	97.6%
Risk-free interest rate	4.2%	4.1%
Dividend yield	0.0%	0.0%

Stock Options

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding balance as of December 31, 2025	6,186,318	$ 10.00	9.5	$ 14,715
Granted	687,164	15.58		
Exercised	(8,174)	10.95		77
Forfeited or expired	(118,804)	13.03		
Outstanding balance as of September 30, 2026	6,746,504	$ 10.51	8.8	$ 28,654
Vested and expected to vest as of September 30, 2026	6,746,504	$ 10.51	8.8	$ 28,654
Exercisable as of September 30, 2026	2,009,734	$ 8.99	8.6	$ 11,179

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and September 30, 2025 was $13.01 and $6.87, respectively. 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 ordinary shares for those stock options that had an exercise price lower than the fair value of the Company's ordinary shares.

Restricted Stock Units

The Company's RSUs have service-based vesting conditions and vest over a four-year period with one quarter of the RSUs vesting on the anniversary of the grant date and the remainder vesting quarterly thereafter, during which time all unvested shares are subject to forfeiture by the Company in the event the holder's service with the Company voluntarily or involuntarily terminates.

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

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2025	741,454	$ 9.04
Granted	—	—
Vested	(220,070)	7.94
Forfeited	(6,179)	13.21
Unvested balance as of September 30, 2026	515,205	$ 9.46

No RSUs were granted during the nine months ended September 30, 2026. The weighted average grant date fair value of RSUs granted during the nine months ended September 30, 2025 was $6.16. The total fair value of shares vested for the nine months ended September 30, 2026 was $1.7 million. No shares vested during the nine months ended September 30, 2025.

Restricted Stock Awards

The Company's RSAs generally have service-based vesting conditions over a four-year period, with one quarter of the RSAs vesting on the anniversary of the grant date and the remainder vesting monthly thereafter. All unvested awards are subject to forfeiture in the event the holder's service with the Company voluntarily or involuntarily terminates.

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

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2025	82,129	$ 2.76
Granted	—	—
Vested	(22,286)	2.77
Forfeited	—	—
Unvested balance as of September 30, 2026	59,843	$ 2.76

No RSAs were granted during the nine months ended September 30, 2026. The weighted average grant date fair value of RSAs granted during the nine months ended September 30, 2025 was $9.55. The total fair value of shares vested for the nine months ended September 30, 2026 was less than $0.1 million. 24,781 awards vested during the nine months ended September 30, 2025.

Parascent Warrant Obligation

Prior to the ADC Option Agreement Termination (as defined below), under the terms of the Paragon Option Agreements (as defined below), Parascent was entitled to a grant of warrants to purchase in the aggregate a number of shares equal to 1.00% of the then outstanding shares of the Company's ordinary shares, on a fully diluted basis, on December 31, 2026, at the fair market value determined by the Board of Directors (the "Parascent Warrant Obligation"). Parascent is an entity formed by Paragon as a vehicle to hold equity in the Company in order to share profits with certain employees of Paragon.

The Company and Paragon terminated the ADC Paragon Option Agreement on March 26, 2026 (the "ADC Option Agreement Termination"). In accordance with the ADC Option Agreement Termination, the Company granted 34,566 warrants to Parascent with a grant date of March 26, 2026. Parascent's warrant has a service inception period for the grant preceding the grant date, with the full award being vested as of the grant date with no post-grant date service requirement.

The Parascent warrants were liability-classified and after the initial recognition, the liability was adjusted to fair value using an option-pricing model at the end of each reporting period, with changes in fair value recorded in the condensed consolidated statement of operations and comprehensive loss. Upon termination, the warrants are equity classified and are no longer subject to remeasurement at fair value.

There were no outstanding liability classified warrants to revalue as of September 30, 2026. The following table summarizes the assumptions used in calculating the fair value of the warrants as of September 30, 2025:

Expected term (in years)	10.0
Expected volatility	99.8%
Risk-free interest rate	4.2%
Dividend yield	0.0%

Share-Based Compensation Expense

The following table summarizes the classification of the Company's share-based compensation expense in the condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
General and administrative	$ 2,339	$ 6,749	$ 1,172	$ 5,250
Research and development	1,881	5,549	813	3,305
Total share-based compensation expense	$ 4,220	$ 12,298	$ 1,985	$ 8,555

The following table summarizes the total unrecognized compensation cost (in thousands) and weighted average recognition period for the Company's awards as of September 30, 2026:

	Total Unrecognized Compensation	Weighted Average Recognition Period
Unvested stock options	$ 40,756	2.9 years
Unvested RSAs	$ 164	2.0 years
Unvested RSUs	$ 4,802	2.9 years

The following table summarizes the award types of the Company's share-based compensation expense in the condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
Stock options	$ 3,680	$ 10,301	$ 1,789	$ 5,924
RSAs	21	61	35	238
RSUs	416	1,238	170	366
ESPP	103	275	—	—
Parascent warrant obligation	—	423	(9)	2,027
Total share-based compensation expense	$ 4,220	$ 12,298	$ 1,985	$ 8,555

10. Income Taxes

There was no income tax provision recorded for the three and nine months ended September 30, 2026 and September 30, 2025, therefore, the Company's effective income tax rate was 0.0% for the three and nine months ended September 30, 2026 and September 30, 2025. The effective income tax rate for the three and nine months ended September 30, 2026 and for the three and nine months ended September 30, 2025 differed from the 21% federal statutory rate due primarily to the valuation allowance maintained against the Company's net deferred tax assets.

11. License Agreements

Paragon Option Agreements

In September 2024, the Company entered into the Antibody Paragon Option Agreement with Paragon and Parascent for CR-001, with the selected targets PD-1 and VEGF (the "Antibody Paragon Option Agreement"). In October 2024, the Company entered into the ADC Paragon Option Agreement with Paragon and Parascent for CR-002, with an undisclosed target (as amended, the "ADC Paragon Option Agreement" and, together with the Antibody Paragon Option Agreement,

the "Paragon Option Agreements"). Under the Paragon Option Agreements, the Company had the exclusive option (an "Option"), on a Research Program-by-Research Program basis, to enter into a separate agreement with Paragon consistent with a set of pre-negotiated terms. On March 18, 2025, the Company exercised its option for CR-001 under the Antibody Paragon Option Agreement and entered into the license agreement for CR-001 on April 28, 2025 (the "CR-001 License Agreement"), upon which the material obligations under the Antibody Paragon Option Agreement were completed. On September 26, 2025, the Company exercised its option for CR-002 under the ADC Paragon Option Agreement and entered into a license agreement with Paragon on November 5, 2025 (the "CR-002 License Agreement"). The Company will be required to make non-refundable milestone payments to Paragon of up to $22.0 million under the CR-001 License Agreement and up to $46.0 million under the CR-002 License Agreement upon the achievement of certain clinical development and regulatory milestones, as well as tiered royalty payments in the low-to-mid single-digits beginning on the first commercial sale of each developed product.

On April 28, 2025, the Company entered into an amended and restated ADC Paragon Option Agreement to add undisclosed targets for the product candidate formerly referred to as CR-003 ("Former CR-003"), pursuant to which Paragon agreed to execute a mutually agreed research plan for those targets aimed at producing a potential product candidate to be licensed for further development, manufacture, and commercialization by the Company. On February 24, 2026, the Company provided notice to Paragon of its intention to terminate the ADC Paragon Option Agreement and the agreement terminated on March 26, 2026. The Company will no longer license intellectual property rights with respect to Former CR-003 following the ADC Option Agreement Termination.

Under the terms of the Paragon Option Agreements, Paragon agreed to perform certain research activities to discover, generate, identify, and characterize one or more antibody candidates, in the case of the Antibody Paragon Option Agreement, and one or more antibody drug conjugates, in the case of the ADC Paragon Option Agreement, directed to certain mutually agreed therapeutic targets of interest to the Company (each, a "Research Program"). The Paragon Option Agreements required the Company, Paragon, and Parascent to develop a research plan for each target that includes design, modeling, synthesis, evaluation, and other mutually agreed activities (each, a "Research Plan"), which activities primarily included performing preclinical studies. Paragon performed the activities set forth in each Research Plan on the timelines set forth in such Research Plan and in compliance with a mutually agreed budget. When Paragon and Parascent produced an antibody or ADC, as applicable, against a selected target, and upon the completion of each Research Program, Paragon and Parascent delivered to the Company a data package that included sequence information for all then-existing antibodies or ADCs, as applicable, and information directed to such target.

Under the Paragon Option Agreements, the Company was also responsible for certain additional development costs incurred by Paragon. The Company expensed fees incurred under the Paragon Option Agreements as the associated costs were incurred when the underlying services were rendered. Such amounts are classified within research and development expenses and general and administrative expenses in the accompanying condensed consolidated statement of operations and comprehensive loss. The following is a summary of expenses related to the development costs and license fees related to the Paragon Option Agreements recorded within the condensed consolidated statements of operations for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
Research and development expense	$ 3,000	$ 5,500	$ 6,184	$ 19,217
General and administrative expense	—	—	89	569
Total Paragon expenses	$ 3,000	$ 5,500	$ 6,273	$ 19,786

There was no balance and $0.1 million related to Paragon included in related party accounts payable and other current liabilities within the condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025, respectively.

Additionally, as part of the Paragon Option Agreements, on each of December 31, 2025 and December 31, 2026, the Company agreed to grant Parascent warrants to purchase an aggregate number of shares equal to 1.00% of its outstanding share capital as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying ordinary shares on each respective grant date. Accordingly, the Company issued 402,731 warrants to Parascent on December 31, 2025. In connection with the ADC Option Agreement Termination, the Company issued 34,566 warrants to Parascent on March 26, 2026 (see Note 9).

The Company concluded that the rights obtained under the Paragon Option Agreements represent asset acquisitions whereby the underlying assets comprise in-process research and development assets with no alternative future use. The Paragon Option Agreements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. The research initiation fees represent a one-time cost on a research program-by-research program basis for accessing research services or resources with benefits that are expected to be consumed in the near term, therefore the amounts paid are expensed as part of research and development costs immediately. Amounts paid as reimbursements of on-going development cost, monthly development cost fee and additional development expenses incurred by Paragon due to work completed for selected targets prior to the effective date of the Paragon Option Agreements that associated with services being rendered under the related Research Programs is recognized as research and development expense when incurred.

CR-001 License Agreement

On April 28, 2025, the Company entered into the CR-001 License Agreement with Paragon for all antibodies discovered, generated, identified, or characterized by Paragon in the course of performing the CR-001 research program directed to PD-1 and VEGF, antibodies created by the Company derived from the licensed antibodies and directed to PD-1 and VEGF, and products that comprise the foregoing consistent with the pre-negotiated terms agreed to upon execution of the Paragon Option Agreements, pursuant to which Paragon granted the Company a royalty-bearing, worldwide, exclusive, and sublicensable license with respect to certain inventions, patent rights, sequence information, and other intellectual property rights related to monospecific antibodies directed at the VEGF and PD-1 targets (the "Licensed Antibody Technology") to use, make, sell, import, export, and otherwise exploit certain licensed antibodies, derived antibodies, products, multispecific antibodies, and multispecific products in the field of prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas (the "field") worldwide (the "territory"). Under the terms of the CR-001 License Agreement, the Company is obligated to pay Paragon up to $22.0 million based on specific development and regulatory milestones, including $2.5 million paid in February 2026 upon the first dosing of a patient in a Phase 1 trial, $3.0 million paid in August 2026 upon the first dosing of a patient in a Phase 2 trial, and a further milestone payment of $5.0 million due upon the first dosing of a patient in a Phase 3 trial. Following the execution of the CR-001 License Agreement, the Company is solely responsible for, and has sole authority and control over, all aspects of the development, manufacturing, and commercialization of product candidates under the CR-001 program, including regulatory strategy, communications, filings, and activities (including clinical trials). Paragon also granted the Company a royalty-bearing, worldwide, non-exclusive, sublicensable right and license under the Licensed Antibody Technology to use, make, sell, import, export, or otherwise exploit certain multispecific antibodies and products targeting PD-1 and VEGF. In addition, the following summarizes other key terms of the CR-001 License Agreement:

- Paragon will not conduct any new campaigns that generate PD-1 and VEGF and monospecific antibodies in the field for at least five years.
- Paragon may pursue the development and commercialization of multispecific antibodies and products directed at the PD-1 and VEGF and targets in the field and in the territory and the Company has a right of first negotiation for any such multispecific antibodies and products proposed by Paragon for a period of five years from the execution of the CR-001 License Agreement. If the Company does not exercise its right of first negotiation, or if the parties are unable to agree on a definitive agreement, Paragon may proceed without any obligations to the Company with respect to the right of first negotiation, and the Company's non-exclusive license will exclude any multispecific antibodies and products that were the subject of the right of first negotiation.
- The Company will pay Paragon a low-to-mid single-digit percentage royalty based on annual net sales of the products in the field and in the territory, and a mid single-digit percentage royalty based on annual net sales of the multispecific products in the field and in the territory, subject to a 30% reduction if there is no valid patent covering the product in the country.
- The royalty term ends on the later of (i) the twelfth anniversary of the date of first commercial sale of a product or multispecific product or (ii) the expiration of the last-to-expire valid patent covering such product or multispecific product in the country at issue.
- The CR-001 License Agreement may be terminated on 60 days' notice by the Company, upon material breach without cure; and to the extent permitted by law, upon a party's insolvency or bankruptcy.

- The Company will control the preparing, filing, prosecuting, and maintenance of patents licensed to the Company under the CR-001 License Agreement.

- The Company shall have the right to grant sublicenses under the CR-001 License Agreement, provided that (i) any sublicense agreement is consistent with all relevant terms, conditions, and restrictions of the CR-001 License Agreement, (ii) the Company provides Paragon with a copy of each sublicense agreement and any amendments thereto within 30 days following execution thereof and (iii) the Company remains responsible for all payments and obligations due under the CR-001 License Agreement.

On December 2, 2025, the Company and Paragon entered into Amendment No. 1 to the CR-001 License Agreement to amend certain terms of the CR-001 License Agreement for the sole purpose of accommodating and aligning with the sublicense for the CR-001 License Agreement with Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. ("Kelun") discussed below.

CR-002 License Agreement

On November 5, 2025, the Company entered into the CR-002 License Agreement for all ADCs discovered, generated, identified or characterized by Paragon in the course of performing the CR-002 research program directed to PD-L1, ADCs created by the Company derived from the licensed ADCs and directed to PD-L1, and products that comprise the foregoing with Paragon consistent with the pre-negotiated terms agreed to upon execution of the ADC Paragon Option Agreement, pursuant to which Paragon granted the Company a royalty-bearing, worldwide, exclusive and sublicensable license with respect to certain inventions, patent rights, sequence information and other intellectual property rights related to ADCs directed at PD-L1 and VEGF (the "Licensed ADC Technology") to develop, manufacture, commercialize and otherwise exploit certain ADCs and products targeting PD-L1 in the field of prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas worldwide. Under the terms of the CR-002 License Agreement, the Company is obligated to pay Paragon up to $46.0 million based on specific development and regulatory milestones, including a $5.0 million fee for the nomination of a development candidate that was paid in October 2025 and a future milestone payment of $5.0 million upon the first dosing of a patient in a Phase 1 trial. Following the execution of the CR-002 License Agreement, the Company is solely responsible for, and has sole authority and control over, all aspects of the development, manufacturing and commercialization of CR-002, including regulatory strategy, communications, filings and activities (including clinical trials). In addition, the following summarizes other key terms of the CR-002 License Agreement:

- The Company will pay Paragon a low-to-mid single-digit percentage royalty based on annual net sales of the products in the field and in the territory, subject to a 30% reduction if there is no valid patent covering the product in the country.

- The royalty term ends on the later of (i) the twelfth anniversary of the date of first commercial sale of a product or (ii) the expiration of the last-to-expire valid patent covering such product in the country at issue.

- The CR-002 License Agreement may be terminated on 60 days' notice by the Company, on material breach without cure; and to the extent permitted by law, on a party's insolvency or bankruptcy.

- The Company will control the preparing, filing, prosecuting and maintenance of patents licensed to the Company under the CR-002 License Agreement.

- The Company shall have the right to grant sublicenses under the CR-002 License Agreement, provided that (i) any sublicense agreement is consistent with all relevant terms, conditions and restrictions of the CR-002 License Agreement, (ii) the Company provides Paragon with a copy of each sublicense agreement and any amendments thereto within 30 days following execution thereof and (iii) the Company remains responsible for all payments and obligations due under the CR-002 License Agreement.

Kelun License Agreements

On December 2, 2025, the Company entered into two license agreements with Kelun, each of which is described below.

Kelun CR-001 License Agreement

On December 2, 2025, the Company and Kelun entered into a license agreement (the "Kelun CR-001 License Agreement") under which the Company granted Kelun an exclusive, royalty-bearing license to research, develop, manufacture and commercialize CR-001 in greater China (including mainland China, Hong Kong, Macau and Taiwan) (collectively, the "SKB Territory"). The Company retains all rights to CR-001 outside the SKB Territory.

Under the Kelun CR-001 License Agreement, Kelun is responsible for development, manufacturing, regulatory and commercial activities for CR-001 in the SKB Territory, and is obligated to use commercially reasonable efforts to develop and commercialize at least one CR-001 product candidate in the SKB Territory.

Kelun paid or will pay the Company the following:

- $20.0 million within 30 days of signing;
- up to $30.0 million in development and regulatory milestone payments; and
- tiered royalties ranging from low- to mid-single digit percentages based on annual net sales in the SKB Territory, subject to customary reductions and a royalty floor on reductions.

The Kelun CR-001 License Agreement includes the provision of the initial supply of CR-001 drug product by the Company, a data-sharing framework, know-how and manufacturing technology transfer provisions, intellectual property provisions, and customary termination rights, including reversion and license-back mechanics in specified circumstances.

In July 2026, Kelun achieved a milestone event upon initiating a combination study under the Kelun CR-001 License Agreement, triggering a $5.0 million payment obligation by the Company. Accordingly, the Company paid $4.5 million to Kelun in August 2026 and $0.5 million of withholding taxes was remitted to tax authorities on Kelun's behalf.

The Kelun CR-001 License Agreement is in the scope of ASC 606, *Revenue from Contracts with Customers*. The Company concluded that the Kelun CR-001 License Agreement contains two performance obligations for the transfer of an exclusive license and the provision of an initial supply of CR-001 as the two services are distinct within the context of the contract.

The Company determined the transaction price under ASC 606 to be $15.0 million, which includes Kelun's $20.0 million payment to the Company upon signing, adjusted for a $5.0 million payment from the Company to Kelun as consideration upon achievement of a developmental milestone related to Kelun's initiation of a combination study. Of the $15.0 million transaction price, $4.2 million was allocated to the initial supply performance obligation and $10.8 million was allocated to the license performance obligation, which was recognized at a point in time during the year ended December 31, 2025.

The transaction price was allocated to the two performance obligations on a relative estimated standalone selling prices utilizing market data. The standalone selling price of the performance obligations were estimated using a market approach that maximized the use of observable inputs.

The Company recognized $3.1 million and $4.2 million of revenue allocated to the provision of the initial supply during the three and nine months ended September 30, 2026, respectively, as the Company transferred control of the initial supply. All revenues recognized during the nine months ended September 30, 2026 were previously included as a contract liability as of December 31, 2025.

As of September 30, 2026, the $30.0 million in development and regulatory milestone payments are fully constrained as variable consideration due to the uncertainty associated with the occurrence of the underlying events that would trigger the development and regulatory milestone consideration and therefore are not included in the transaction price of the arrangement. The Company will reassess this conclusion at each subsequent reporting period and will only include amounts associated with development or regulatory milestones in the transaction price when, or if, the variable consideration is determined to be released from constraint.

As of September 30, 2026, the Company has not recognized any royalties under its licensing agreement. Royalties qualify for the sales-and-usage exemption under ASC 606 as (i) royalties are based strictly on the sale-and-usage by the licensee and (ii) a license of intellectual property is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned under the terms of a license agreement in the period the products are sold by the Company's collaborator and the Company has a present right to payment.

SKB105 License and Collaboration Agreement

On December 2, 2025, the Company and Kelun entered into a License and Collaboration Agreement (the "SKB105 License Agreement"), under which Kelun granted the Company an exclusive license to research, develop, manufacture and commercialize SKB105, Kelun's proprietary integrin beta-6-directed antibody-drug conjugate, in all territories outside the SKB Territory (as defined in the SKB105 License Agreement). The Company intends to develop SKB105 as CR-003, a product designation which previously referred to a preclinical ADC asset under the Paragon Option Agreements discussed elsewhere in this Note 11 to the condensed consolidated financial statements.

The Company is responsible for all development, manufacturing, regulatory and commercial activities for SKB105 outside the SKB Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, manufacture (or have manufactured) and commercialize at least one SKB105 product in the United States and at least three major European markets.

Under the SKB105 License Agreement, the Company has paid or agreed to pay Kelun:

- $80.0 million upfront;
- up to $345.0 million in development milestone payments;
- up to $902.5 million in sales-based milestone payments;
- tiered royalties ranging from mid-single digits to low-double digits based on annual net sales, subject to customary reductions and a royalty floor;
- sublicense and divestiture revenue-sharing payments of low double-digit percentages of any sublicense or divestiture consideration on account of SKB105 paid or payable to the Company within 18 months after the effective date of the definitive agreement in connection with any such triggering transaction; and
- a potential payment of low-single digits to low-double digits of any change of control consideration (including cash or any other consideration) received by equity holders of the Company if the Company undergoes a qualifying change-of-control transaction within 24 months.

The Company concluded that the rights obtained under the SKB105 License Agreement represent an asset acquisition whereby the underlying licensed intellectual property is in-process research and development intellectual property with no alternative future use. The SKB105 License Agreement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license.

The Company did not record any research and development expense for the SKB105 License Agreement for the three and nine months ended September 30, 2026. In January 2026, $8.0 million of withholding taxes was remitted to tax authorities on Kelun's behalf and is included within purchase of research and development license on the consolidated statement of cash flows. A portion of the nonrefundable upfront $80.0 million payment represents costs for SKB105 drug supply that Kelun is obligated to provide to the Company that has not been received as of September 30, 2026, and will be used in future research and development activities. The Company recorded $1.8 million within prepaid expenses and other current assets on its consolidated balance sheet as of September 30, 2026, and will recognize the amounts into research and development expense as the SKB105 drug supply is received from Kelun throughout the remainder of 2026.

As of September 30, 2026, no development milestones had been triggered.

12. Leases

In May 2025, the Company entered into a noncancelable operating sublease agreement with Nano Dimension USA Inc. ("Sublandlord") whereby the Company sublets approximately 25,000 square feet of office space located in Waltham, Massachusetts ("Waltham Sublease"). The sublease commencement date was June 1, 2025, with an initial term of 45 months.

In September 2026, the Company entered into an operating lease with NWALP PHOP Property Owner LLC ("Landlord") for approximately 15,000 square feet of office space in Waltham, Massachusetts. The lease commencement date was September 15, 2026, and the lease has an initial term of twenty nine and one half months. The total undiscounted lease payments over the term are approximately $1.3 million.

Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate when measuring

operating lease liabilities as discount rates were not implicit or readily determinable. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

As of September 30, 2026, the Company had $2.3 million of operating lease ROU assets, short term lease liabilities of $0.7 million and long term lease liability of $1.7 million on its condensed consolidated balance sheets. As of September 30, 2026, the operating lease arrangements had a weighted average remaining lease term of 2.42 years and a discount rate of 10.6%.

As of September 30, 2026, the total remaining operating lease payments included in the measurement of lease liabilities was as follows (in thousands):

Period ended December 31		
2026 (remainder of the year)	$	156
2027		1,117
2028		1,315
2029		223
Total undiscounted lease payments		2,811
Less: imputed interest		(353)
Total present value of operating lease liability	$	2,458

13. Commitments and Contingencies

401(k) Plan

The Company maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code of 1986 (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the 401(k) Plan may be made at the discretion of management. For the three and nine months ended September 30, 2026 and September 30, 2025, the Company has not recorded any expense related to 401(k) Plan match contributions.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2026.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of September 30, 2026, the Company was not a party to any material legal proceedings or claims.

Cell Line License Agreement

In October 2024, the Company entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology"), and media and feeds to make, have made, use, sell, and import 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"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the CR-001 and CR-002 programs.

In consideration for the license, the Company agreed to pay WuXi Biologics a non-refundable license fee of $150,000, which was recognized as a research and development expense during the period from September 19, 2024 (inception) to December 31, 2024. Additionally, to the extent that the Company manufactures its commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, the Company is required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon six months' prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by the Company that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

14. Net Loss per Share

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

	Three Months Ended September 30, 2026			Three Months Ended September 30, 2025		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted
Ordinary Shares	$ (35,127)	39,056,224	$ (0.90)	$ (20,947)	16,540,771	$ (1.27)
Series A Preferred Shares [1]	(2,599)	2,890	$ (899.31)	(3,660)	2,890	$ (1,266.44)
Net loss	$ (37,726)			$ (24,607)		

	Nine Months Ended September 30, 2026			Nine Months Ended September 30, 2025		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted
Ordinary Shares	$ (79,002)	33,360,473	$ (2.37)	$ (52,391)	6,640,402	$ (7.89)
Series A Preferred Shares [1]	(6,844)	2,890	$ (2,368.17)	(9,154)	1,160	$ (7,891.38)
Net loss	$ (85,846)			$ (61,545)		

(1) The weighted-average number of shares of as-converted Series A Preferred Shares used in the loss allocation was 2,890,000 for the three and nine months ended September 30, 2026 and 2,890,000 and 1,160,219 for the three and nine months ended September 30, 2025, respectively.

For the computation of basic net loss per share attributable to ordinary shareholders, the amount of weighted-average ordinary shares outstanding excludes all shares of unvested restricted stock and early-exercised stock options as such shares are not considered outstanding for accounting purposes until vested. The amount of weighted-average shares outstanding includes the pre-funded warrants as the exercise price is negligible and these warrants are fully vested and exercisable. The potential ordinary shares that were excluded from the computation of diluted net loss per share attributable to ordinary shareholders for the periods presented because including them would have had an anti-dilutive effect were as follows:

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
Outstanding unvested restricted stock units	515,205	515,205	438,386	438,386
Outstanding unvested restricted stock awards	59,843	59,843	94,083	94,083
Outstanding and issued stock options	6,746,504	6,746,504	4,094,237	4,094,237
Total	7,321,552	7,321,552	4,626,706	4,626,706

15. Related Party Transactions

Paragon and Parascent each beneficially own less than 5% of the Company's share capital through their respective holdings of the Company's ordinary shares. Fairmount beneficially owns more than 5% of the Company's capital, currently has two representatives appointed to the Board and beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers of Paragon. The Company determined Paragon and Parascent were related parties based on the nature of these relationships.

The Company had no related party accounts payable and other current liabilities as of September 30, 2026. As of December 31, 2025, the Company had $0.1 million of accrued research and development costs and an immaterial amount of accrued general and administrative costs.

16. Asset Sale

On April 2, 2026, the Company entered into an asset purchase agreement for its GMI-1687 and GMI-1271 technology, including intellectual property, which had been acquired as part of the reverse merger and was not in active development, for cash consideration of $1.8 million. Additional contingent consideration is included in the asset purchase agreement and is dependent on future development, regulatory, and sales milestones. The Company recorded the cash consideration of $1.8 million as a gain on sale of a nonfinancial asset under ASC 610-20. As there was no recorded value for the assets sold, $1.8 million was recognized as other income during the nine months ended September 30, 2026 within the condensed consolidated statement of operations and comprehensive loss. No amounts were recognized within the condensed consolidated statement of operations and comprehensive loss during the three months ended September 30, 2026. The Company has fully constrained the variable consideration as of September 30, 2026.

17. Segment Reporting

The Company has one reportable segment relating to the research and development of its research programs, CR-001, CR-002, and CR-003. The Company's CODM, its Chief Executive Officer, manages the Company's operations on a company-wide basis for the allocation of resources and the assessment of performance. The Company's measure of segment profit or loss used to assess performance and allocate resources is net loss and comprehensive loss. Although the Company's financial reporting package that is reviewed and approved by the CODM disaggregates significant expenses such as program-level external research and development costs, personnel costs, including share-based compensation expense, and professional and consulting fees, all decisions made by the CODM are based upon reviewing operating metrics and performance indications at the Company-wide level. The CODM uses net loss to evaluate loss generated from the Company's business activities in deciding how to allocate company resources and monitoring budget versus actual results. Assets are also managed on a Company-wide basis.

The table below is a summary of the segment loss, including significant segment expenses (in thousands):

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
License revenue	$ 3,117	$ 4,156	$ —	$ —
Less:				
CR-001 external research and development costs	19,727	31,111	8,379	18,146
CR-002 external research and development costs	3,275	12,971	1,510	5,990
Discovery external research and development costs[1]	227	339	292	1,724
Personnel costs	12,515	34,403	7,436	19,873
Milestone and license fees[2]	3,000	5,500	5,595	7,415
Professional and other fees[3]	4,280	12,602	2,673	7,992
Other expense (income)[4]	(2,181)	(6,924)	(1,278)	405
Net loss and comprehensive loss	$ (37,726)	$ (85,846)	$ (24,607)	$ (61,545)

(1) Discovery external research and development costs include costs associated with CR-003 and other candidate discovery activities.

(2) 2026 amounts for milestone and license fees includes payments for $2.5 million and $3.0 million to Paragon related to the first dosing of a patient in a Phase 1 trial and a Phase 2 trial, respectively, for CR-001 per the CR-001 License Agreement.

(3) Professional and other fees includes professional fees, consulting fees, office and facilities expense, and miscellaneous other expense.

(4) Other expense (income) includes interest income and interest expense.

For the three and nine months ended September 30, 2026, all of the Company's revenues were earned from a license agreement with a single customer located in China. As of September 30, 2026, all of the Company's long-lived assets are located in the United States.

18. Subsequent Events

The Company has evaluated events and transactions occurring subsequent to September 30, 2026 through the date at which the financial statements were issued and concluded that no subsequent events have occurred that require disclosure.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the related notes included in Part I - Item 1 of this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2026 (this "Quarterly Report"). The following discussion contains forward-looking statements that reflect our current plans, estimates and beliefs and words such as "may," "might," "will," "would," "shall," "objective," "intend," "target," "should," "could," "can," "expect," "anticipate," "believe," "design," "estimate," "forecast," "predict," "potential," "plan," "seek," or "continue" and variations of such words and any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, and similar expressions are intended to identify forward-looking statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Quarterly Report. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," "the Company," "Crescent Biopharma, Inc.," "Crescent," "GlycoMimetics, Inc.," "GlycoMimetics," refers to Crescent Biopharma, Inc. and its consolidated subsidiaries, including Crescent Biopharma Operating Company LLC, taken as a whole.

Overview

We are a clinical-stage biotechnology company focused on delivering the next wave of transformative therapies to bring a brighter future for people living with cancer. We have a bold vision to build the next leading biotechnology oncology company. We are executing across two distinct strategies to build our portfolio to achieve this vision. First, we are developing CR-001 (also known as SKB118), which we refer to as a PD-1 x VEGF bispecific antibody because it is designed to bind both the PD-1 immune checkpoint ("PD-1") and Vascular Endothelial Growth Factor ("VEGF"), which has potential to replace pembrolizumab, marketed by Merck as Keytruda®, as the foundational immuno-oncology backbone; second, we are building a robust portfolio of potentially best-in-class antibody drug conjugates ("ADCs"). Importantly, as we execute on these two strategies, we intend to combine CR-001 and ADC therapies to create what we believe will be best-in-class synergistic combinations to transform care for multiple types of cancer. In the first quarter of 2026, we initiated a global Phase 1/2 trial of CR-001 (the "ASCEND trial"), with initial data expected in the first quarter of 2027, and, through our partner Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. ("Kelun"), a Phase 1/2 trial of CR-003 (also known as SKB105) as a monotherapy in China, with proof-of-concept data expected in the first quarter of 2027. Additionally, Kelun initiated multiple Phase 2 clinical studies in China of its trophoblast cell-surface antigen 2 (TROP2)-directed ADC sacituzumab tirumotecan ("sac-TMT") in combination with CR-001 to evaluate the safety, tolerability, and efficacy in patients with non-small cell lung cancer ("NSCLC") and other solid tumors, with initial data from NSCLC patients anticipated in mid-2027 (second or third quarter). We also initiated a global Phase 1/2 trial of CR-002 (the "APOLLO trial") in the fourth quarter of 2026, with initial data expected in the second half of 2027.

We initiated ASCEND, a global Phase 1/2 trial of CR-001 in up to eight solid tumor types in the first quarter of 2026. We believe that, because CR-001 incorporates the functional properties of ivonescimab, early clinical data from ivonescimab can serve as important validation of potential effectiveness and tolerability of both ivonescimab and CR-001, thereby allowing us to move quickly into late-stage development with a level of speed and confidence that would not exist if CR-001 did not incorporate the PD-1 and VEGF binding affinity, potency, and cooperative pharmacology of ivonescimab. In the first quarter of 2027, we anticipate sharing initial monotherapy data from ASCEND, including preliminary antitumor response as measured by overall response rate ("ORR") from a first-line NSCLC cohort of up to 12 patients and the safety, tolerability, pharmacokinetics ("PK") and pharmacodynamic ("PD") data from more than 125 treatment-naïve and previously-treated patients across multiple solid tumor types. In mid-2027 (second or third quarter), we plan to share initial standard of care chemotherapy combination data from ASCEND.

CR-002 is a PD-L1-directed ADC designed to deliver a topoisomerase toxin to cancer cells that express PD-L1, a cell surface protein that suppresses T-cell activation. PD-L1 expression is elevated in numerous solid tumors compared to normal tissues, making it an attractive ADC target. In October 2026, CR-002 received allowance to proceed under an Investigational New Drug Application ("IND") from the FDA, and we initiated the global Phase 1/2 APOLLO trial in the fourth quarter of 2026 in patients with advanced solid tumors, including NSCLC, head and neck squamous cell carcinoma, and various gastrointestinal and gynecological tumors. Initial data are expected in the second half of 2027.

In December 2025, we announced a partnership with Kelun, a leading Chinese biotech company with commercially approved ADCs, to acquire exclusive rights to SKB105, an integrin beta-6 ("ITGB6") directed ADC, outside of mainland China, Hong Kong, Macau, and Taiwan (collectively, "Greater China"). We intend to develop SKB105 as CR-003, a product designation which previously referred to a preclinical ADC asset under the Amended and Restated ADC Discovery and Option Agreement, dated April 28, 2025 (the "ADC Paragon Option Agreement"). ITGB6 is a target with emerging clinical data generated by third party ADCs. We believe that CR-003 has the potential to deliver potent antitumor activity based on its improved potency and half-life in preclinical models. A Phase 1/2 trial of CR-003 was initiated in the first quarter of 2026 in China. We believe that CR-002 and CR-003 have the potential to provide therapeutic benefit both when used as monotherapies and in combination with CR-001.

Since our inception in September 2024, we have devoted substantially all of our resources to raising capital, organizing and staffing the Company, business and scientific planning, conducting discovery and research activities, establishing arrangements with third parties, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the reverse recapitalization and merger with GlycoMimetics, Inc. and sales of equity and debt securities (see Note 8 to the condensed consolidated financial statements above for more information).

We have incurred operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of any programs we may develop. We incurred a net loss of $37.7 million and $85.8 million for the three and nine months ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $257.7 million. For the nine months ended September 30, 2026, we have used net cash of $55.3 million for our operating activities.

As of September 30, 2026, we had cash and cash equivalents of $289.4 million. We expect that our existing cash will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Quarterly Report. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure.

Impact of General Economic Risk Factors on Crescent'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 increases in inflation, fluctuating interest rates, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), including as a result of bank failures, geopolitical factors, including the ongoing conflicts in Iran and elsewhere in the Middle East and between Russia and Ukraine and the responses thereto, 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, 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 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. For additional information, see Part II, Item 1A, "*Risk Factors*."

Components of Results of Operations

Revenue

Our revenues to date have been generated through the Kelun CR-001 License Agreement. We may recognize revenue over the expected performance period under the agreement. The terms of this agreement include one or more of the following types of payments: non-refundable license fees, payments based on the achievement of specified milestones, and royalties on any net product sales. To date, we have received a non-refundable upfront payment for the license to CR-001. We expect that our revenue for the next several years will be derived primarily from our current license agreements and any additional licensing agreements that we may enter into in the future.

To date, we have not generated revenue from product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales or payments from existing or future collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot

predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

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:

- costs of funding research performed by third parties, including Paragon, that conduct research and development activities on our behalf and services rendered under the related Paragon option and license agreements for CR-001, CR-002, CR-003, and other discovery candidates;
- expenses incurred in connection with continuing our current research programs and discovery-phase development of any programs we may identify, including under future agreements with third parties, such as consultants and contractors; and
- personnel-related expenses, including recruiting costs, salaries, bonuses, benefits, and equity-based compensation expense.

We expense research and development costs as incurred. Research and development expenses recorded in connection with services provided by Paragon under (i) the Antibody Discovery and Option Agreement, dated September 19, 2024 (the "Antibody Paragon Option Agreement") and the ADC Paragon Option Agreement (together with the Antibody Paragon Option Agreement, the "Paragon Option Agreements"), and (ii) the CR-001 License Agreement with Paragon, dated April 28, 2025, as amended on December 2, 2025 (the "CR-001 License Agreement"), and CR-002 License Agreement with Paragon, dated November 5, 2025 (the "CR-002 License Agreement"), in our condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2026, was $3.0 million and $5.5 million, respectively, and $6.2 million and $19.2 million for the three and nine months ended September 30, 2025, respectively.

We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to the continued development of our programs, developing any future programs, including investments in manufacturing, as we advance any program we may identify and continue to conduct clinical trials. The success of programs we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies;
- submission and maintenance of INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any programs we may develop;
- successful enrollment and completion of clinical trials;
- positive results from our future clinical trials that support a finding of safety, purity, potency and/or effectiveness, acceptable pharmacokinetics profile, and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities; and
- maintenance of a continued acceptable safety, tolerability, and efficacy profile of any programs we may develop following approval.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including recruiting costs, salaries, bonuses, benefits, and equity-based compensation, for individuals in our executive, finance, legal, operations, business development, and other administrative functions. Other significant general and administrative expenses include

legal fees relating to corporate matters and patent-related activities, insurance costs, information technology, and professional and consulting fees associated with accounting, audit, tax, and investor and public relations.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount and further establish our office space to support our expected growth. We also expect to incur increased expenses as a public company, including increased costs of accounting, audit, legal, regulatory and tax related services associated with maintaining compliance with U.S. Securities and Exchange Commission ("SEC") requirements, additional director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense)

Other income (expense) includes interest income of $2.2 million and $5.2 million, for the three and nine months ended September 30, 2026, respectively, and $1.3 million and $1.8 million for the three and nine months ended September 30, 2025, respectively, relating to interest from our money market account. Other operating income (expense) includes $1.8 million of other income related to the sale of legacy GlycoMimetics intellectual property assets for the nine months ended September 30, 2026. Also included in other income (expense) is $2.2 million of interest expense incurred for the nine months ended September 30, 2025 relating to our previously outstanding convertible notes with an initial principal amount of $37.5 million ("Convertible Notes") issued to various investors in October 2024, which converted to common stock (now, ordinary shares) and pre-funded warrants upon the close of the Merger.

Income Taxes

No provision for income taxes was recorded for the three and nine months ended September 30, 2026 and September 30, 2025. We recorded a full valuation allowance against our net deferred tax assets as of the balance sheet date, as we believe it is not more likely than not that the benefit will be realized due to our cumulative losses generated to date and expectation of future losses.

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 tax provisions. We have evaluated the OBBBA provisions and estimated their impact on the consolidated financial statements to be immaterial. We will continue to evaluate the full impact of these legislative changes as additional guidance becomes available.

Results of Operations for the Three Months Ended September 30, 2026 Compared to the Three Months Ended September 30, 2025

The following table summarizes our condensed consolidated statement of operations and comprehensive loss for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	$ Change
License agreement revenue	$ 3,117	$ —	$ 3,117
Operating expenses			
Research and development[1]	34,305	20,347	13,958
General and administrative[2]	8,719	5,538	3,181
Total operating expenses	43,024	25,885	17,139
Loss from operations	(39,907)	(25,885)	(14,022)
Other income:			
Interest income	2,181	1,278	903
Total other income	2,181	1,278	903
Net loss and comprehensive loss	$ (37,726)	$ (24,607)	$ (13,119)

(1) Includes related party amount of $3,000 and $6,175 for the three months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $89 for the three months ended September 30, 2026 and September 30, 2025, respectively.

License Agreement Revenue

The following table summarizes our license revenue generated for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	$ Change
License agreement revenue	$ 3,117	$ —	$ 3,117

Revenue of $3.1 million for the three months ended September 30, 2026 consisted of amounts earned for the transfer of a portion of the initial supply of CR-001 to Kelun.

Research and Development Expenses

The following table summarizes our research and development expenses incurred for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	$ Change
External research and development costs:			
CR-001[(1)]	$ 22,712	$ 8,714	$ 13,998
CR-002[(2)]	3,275	6,705	(3,430)
CR-003	227	—	227
Other external research and discovery[(3)]	—	357	(357)
Other research and development costs:			
Personnel-related (including share-based compensation)[(4)]	7,324	4,211	3,113
Office, facilities, and software	481	282	199
Professional and consulting fees	286	78	208
Total research and development expenses	$ 34,305	$ 20,347	$ 13,958

(1) Includes related party amount of $3,000 and $423 for the three months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $5,534 for the three months ended September 30, 2026 and September 30, 2025, respectively.

(3) Includes related party amount of $0 and $226 for the three months ended September 30, 2026 and September 30, 2025, respectively. Other external research and discovery also includes former CR-003 activities, which were previously presented under CR-003.

(4) Includes related party amount of $0 and $(8) for the three months ended September 30, 2026 and September 30, 2025, respectively.

Research and development expenses increased by $14.0 million during the three months ended September 30, 2026 compared to the same period in the prior year as we develop our pipeline and continue to hire resources to support our ongoing and future research and development.

External research and development expenses, including CROs, CMOs, and other third-party preclinical studies and clinical trials expenses, increased by $10.4 million, from $15.8 million for the three months ended September 30, 2025 to $26.2 million during the three months September 30, 2026. The increase is primarily related to increased clinical

development on the global Phase 1/2 ASCEND trial and the costs incurred in preparation for the initiation of the global Phase 1/2 APOLLO trial.

Personnel-related expenses increased by $3.1 million, including a $1.1 million increase in share-based compensation during the three months ended September 30, 2026 compared to the same period in the prior year as we continue to hire employees to support ongoing and future research and development.

For the three months ended September 30, 2026 compared to the same period in the prior year, office, facilities, and software expense increased by $0.2 million and professional and consulting fees increased by $0.2 million, both as a result of continued support of our pipeline.

General and Administrative Expenses

The following table summarizes our total general and administrative expenses for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	$ Change
Personnel-related (including share-based compensation)	$ 5,191	$ 3,225	$ 1,966
Professional and consulting fees	1,744	1,276	468
Office, facilities, and software	1,461	849	612
Legal fees related to our intellectual property[(1)]	323	188	135
Total general and administrative expenses	$ 8,719	$ 5,538	$ 3,181

(1) Includes related party amount of $0 and $89 for the three months ended September 30, 2026 and September 30, 2025, respectively.

General and administrative expenses increased by $3.2 million during the three months ended September 30, 2026 compared to the same period in the prior year. Personnel-related expenses increased by $2.0 million during the three months ended September 30, 2026 compared to the same period in the prior year, primarily as a result of increases in share based compensation and other compensation costs by $1.2 million and $0.8 million, respectively, during the three months ended September 30, 2026 compared to the same period in the prior year due to our continued hiring of executive and administrative employees.

Professional and consulting fees increased by $0.5 million during the three months ended September 30, 2026 compared to the same period in the prior year as a result of continued support of our pipeline. Office, facilities, and software increased by $0.6 million in continued support of our pipeline.

Interest Income

The following table summarizes our interest income for the periods presented (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	$ Change
Interest income	$ 2,181	$ 1,278	$ 903

Interest income increased by $0.9 million during the three months ended September 30, 2026 compared to the same period in the prior year due to sustained increased levels of cash and cash equivalents during the three months ended September 30, 2026 as compared to the three months ended September 30, 2025.

Results of Operations for the Nine Months Ended September 30, 2026 Compared to the Nine Months Ended September 30, 2025

The following table summarizes our condensed consolidated statement of operations and comprehensive loss for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
License agreement revenue	$ 4,156	$ —	$ 4,156
Operating expenses			
Research and development[1]	71,598	43,059	28,539
General and administrative[2]	25,328	18,081	7,247
Total operating expenses	96,926	61,140	35,786
Other operating income	1,770	—	1,770
Loss from operations	(91,000)	(61,140)	(29,860)
Other income (expense):			
Interest income	5,154	1,780	3,374
Interest expense[3]	—	(2,185)	2,185
Total other income (expense)	5,154	(405)	5,559
Net loss and comprehensive loss	$ (85,846)	$ (61,545)	$ (24,301)

(1) Includes related party amount of $5,923 and $21,244 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $719 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(3) Includes related party amount of $0 and $865 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

License Agreement Revenue

The following table summarizes our license revenue generated for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
License agreement revenue	$ 4,156	$ —	$ 4,156

Revenue of $4.2 million for the nine months ended September 30, 2026 consisted of amounts earned for the transfer of the initial supply of CR-001 to Kelun.

Research and Development Expenses

The following table summarizes our research and development expenses incurred for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
External research and development costs:			
CR-001[1]	$ 36,596	$ 19,412	$ 17,184
CR-002[2]	12,971	11,685	1,286
CR-003	339	—	339
Other external research and discovery[3]	—	2,179	(2,179)
Other research and development costs:			
Personnel-related (including share-based compensation)[4]	19,786	9,355	10,431
Office, facilities, and software	1,301	380	921
Professional and consulting fees	605	48	557
Total research and development expenses	$ 71,598	$ 43,059	$ 28,539

(1) Includes related party amount of $5,500 and $6,663 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $10,514 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(3) Includes related party amount of $0 and $2,040 for the nine months ended September 30, 2026 and September 30, 2025, respectively. Other external research and discovery also includes former CR-003 activities, which were previously presented under CR-003.

(4) Includes related party amount of $423 and $2,027 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

Research and development expenses increased by $28.5 million during the nine months ended September 30, 2026 compared to the same period in the prior year as we develop our pipeline and continue to hire resources to support our ongoing and future research and development.

External research and development expenses, including CROs, CMOs, and other third-party preclinical studies and clinical trials expenses, increased by $16.6 million, from $33.3 million for the nine months ended September 30, 2025 to $49.9 million during the nine months ended September 30, 2026. The increase is primarily related to increased clinical

development on the global Phase 1/2 ASCEND trial and the costs incurred in preparation for the initiation of the global Phase 1/2 APOLLO trial.

Personnel-related expenses increased by $10.4 million during the nine months ended September 30, 2026 compared to the same period in the prior year as we continue to hire employees to support ongoing and future research and development. Share-based compensation increased by $2.2 million during the nine months ended September 30, 2026 compared to the same period in the prior year, primarily as a result of increases in employee awards and partially offset by a decrease in expense related to the Parascent warrants.

For the nine months ended September 30, 2026 compared to the same period in the prior year, office, facilities, and software expense increased by $0.9 million and professional and consulting fees increased by $0.6 million, both as a result of continuing support of our pipeline.

General and Administrative Expenses

The following table summarizes our total general and administrative expenses for the period presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
Personnel-related (including stock-based compensation)[1]	$ 14,617	$ 10,517	$ 4,100
Professional and consulting fees[2]	5,850	5,303	547
Office, facilities, and software	3,798	1,760	2,038
Legal fees related to our intellectual property[3]	1,063	501	562
Total general and administrative expenses	$ 25,328	$ 18,081	$ 7,247

(1) Includes related party amount of $0 and $213 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(2) Includes related party amount of $0 and $150 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

(3) Includes related party amount of $0 and $356 for the nine months ended September 30, 2026 and September 30, 2025, respectively.

General and administrative expenses increased by $7.2 million during the nine months ended September 30, 2026 compared to the same period in the prior year. Personnel-related expenses increased by $4.1 million during the nine months ended September 30, 2026 compared to the same period in the prior year. Increases in personnel-related expenses were primarily the result of our continued hiring of executives and administrative employees, resulting in increases to both share-based compensation and other compensation costs during the nine months ended September 30, 2026 compared to the same period in the prior year by $1.5 million and $2.6 million, respectively.

Professional and consulting fees increased by $0.5 million during the nine months ended September 30, 2026 compared to the same period in the prior year as a result of continued support of our pipeline. Office, facilities, and software increased by $2.0 million, primarily as a result of continued support of our pipeline.

Interest Income

The following table summarizes our interest income for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
Interest income	$ 5,154	$ 1,780	$ 3,374

Interest income increased by $3.4 million during the nine months ended September 30, 2026 compared to the same period in the prior year due to sustained increased levels of cash and cash equivalents during the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025.

Other Income

The following table summarizes our other income for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
Other income	$ 1,770	$ —	$ 1,770

Other income increased by $1.8 million during the nine months ended September 30, 2026 compared to the same period in the prior year due to the sale of the legacy GlycoMimetics intellectual property assets in the current year.

Interest Expense

The following table summarizes our interest expense for the periods presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	$ Change
Interest expense	$ —	$ (2,185)	$ 2,185

Interest expense for the nine months ended September 30, 2025 related to our previously outstanding Convertible Notes with an initial principal amount of $37.5 million issued to various investors in October 2024, which converted to common stock (now, ordinary shares) and pre-funded warrants upon the close of the Merger. No further interest expense is expected following the conversion of the Convertible Notes.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we continue clinical development of our CR-001 and CR-002 programs and continue the preclinical development of our CR-003 program. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the issuance of equity and debt securities.

In June 2025, we raised approximately $142.3 million in net proceeds from the Pre-Closing Financing (as defined in Note 1 to the condensed consolidated financial statements), excluding the previously received proceeds from the Convertible Notes, and received $1.3 million in cash from GlycoMimetics upon consummation of the Merger. Please see Note 1, “Nature of the Business” to the condensed consolidated financial statements for additional information.

In December 2025, we raised approximately $171.9 million in net proceeds from the Private Placement (as defined in Note 8 to the condensed consolidated financial statements).

In July 2026, we raised approximately $133.4 million in net proceeds from the July 2026 Offering (as defined in Note 8 to the condensed consolidated financial statements). For the three months ended September 30, 2026, we raised approximately $11.1 million from sales under our ATM Program (as defined in Note 8 to the condensed consolidated financial statements). Please see Note 8, “Convertible Preferred Shares and Shareholders' Equity (Deficit)” to the condensed consolidated financial statements for additional information.

As of September 30, 2026, we had cash and cash equivalents of $289.4 million.

Our primary use of cash is to fund the development of our product candidates and advance our pipeline. This includes both the research and development costs and the general and administrative expenses required to support those operations. Because we are a clinical-stage biotechnology company, we have incurred significant operating losses since our inception and we anticipate such losses to increase as we continue to pursue clinical development of our product candidates, prepare for the potential commercialization of our product candidates, and expand our development efforts in our pipeline of nonclinical candidates. We expect that our existing cash will be sufficient to fund our operating plans for at least twelve months from the date of this Quarterly Report. We will need to secure additional financing in the future to fund additional research and development and before a commercial drug can be produced, marketed, and sold. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on our company and our operations.

Cash Flows

The following table summarizes our cash flows for the period presented (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Net cash used in operating activities	$ (55,337)	$ (44,792)
Net cash used in investing activities	(6,390)	(726)
Net cash provided by financing activities	138,004	144,124
Net increase in cash, cash equivalents, and restricted cash	$ 76,277	$ 98,606

Net Cash Used in Operating Activities

For the nine months ended September 30, 2026, net cash used in operating activities was $55.3 million, which was primarily attributable to a net loss of $85.8 million, partially offset by non-cash charges of $11.0 million and net cash provided by changes in operating activities of $19.5 million. The changes in operating activities were primarily due to the receipt of proceeds from the Kelun CR-001 License Agreement, as well as an increase in our business activity and timing of vendor invoicing and payments. Non-cash charges primarily consisted of $12.3 million in share-based compensation expense, offset by a $1.8 million gain on the sale of legacy GlycoMimetics intellectual property assets.

For the nine months ended September 30, 2025, net cash used in operating activities was $44.8 million, which was primarily attributable to a net loss of $61.5 million, partially offset by non-cash charges of $10.9 million, and net cash provided by changes in operating activities of $5.9 million. The changes in operating activities were primarily due to an increase in our business activity as well as the timing of vendor invoicing and payments. Non-cash charges primarily consisted of $8.6 million in share-based compensation expense and of $2.2 million non-cash interest expense.

Net Cash Used in Investing Activities

For the nine months ended September 30, 2026, net cash used in investing activities was attributable to the remittance to tax authorities on Kelun's behalf of $8.0 million in withholding taxes related to the SKB105 License Agreement, proceeds received from the sale of legacy GlycoMimetics intellectual property assets of $1.8 million, and $0.2 million of purchases of property and equipment associated with the build-out of the sublease of office space located in Waltham, Massachusetts.

For the nine months ended September 30, 2025, net cash used in investing activities was attributable to purchases of $0.7 million of property and equipment associated with the build out of the sublease of office space located in Waltham, Massachusetts.

Net Cash Provided by Financing Activities

For the nine months ended September 30, 2026, net cash provided by financing activities was $138.0 million, consisting of $135.1 million of net proceeds from the July 2026 Offering, $11.1 million of net proceeds from sales under our ATM Program, $0.3 million in proceeds from the issuance of ESPP shares, and $0.1 million of proceeds for employee stock option exercises, offset by $8.6 million of payments for deferred offering costs related to the Private Placement, the July 2026 Offering, and the ATM Program.

For the nine months ended September 30, 2025, net cash provided by financing activities was $144.1 million, consisting primarily of $143.0 million of net proceeds from the Pre-Closing Financing and $1.3 million of cash acquired in connection with the reverse recapitalization, partially offset by the repurchase of restricted stock awards of $0.2 million.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with CROs, CMOs, and other vendors for preclinical research studies, clinical trials, manufacturing, and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if the contract is cancelled within a specified time, and therefore, are cancellable contracts. We do not expect any such contract terminations and did not have any non-cancellable obligations under these agreements as of September 30, 2026.

See Notes 11, 12, and 13 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report for further information on our licensing agreements with Kelun, our contractual lease obligations for our office in Waltham, Massachusetts, and other commitments, including the commitments under our option and license agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 2 to our consolidated financial statements for the twelve months ended December 31, 2025 included in Part II, Item 8 of our Annual Report. There have been no material changes to our critical accounting policies and estimates that were disclosed in our Annual Report.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 to the condensed consolidated financial statements as of September 30, 2026 included in Part I, Item 1 of this Quarterly Report.

Off-Balance Sheet Arrangements

As of September 30, 2026, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Management's Evaluation of Disclosure Controls and Procedures

Management recognizes that any controls and procedures, as defined in Rules 13a-15(e) and Rule 15d-15(e) under the Exchange Act, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. In addition, the design of disclosure controls and procedures must reflect that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. Based on the foregoing evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2026.

Changes in Internal Control over Financial Reporting

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

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us that could reasonably be expected to have a material adverse effect on our results of operations, financial condition, or cash flows.

Item 1A. Risk Factors

Our business faces significant risks and uncertainties. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage biotechnology company with a limited operating history on which to assess our business; we have not completed any clinical trials, have no products approved for commercial sale, have historically incurred losses, and we anticipate that we will continue to incur significant losses for the foreseeable future. Moreover, we have never generated revenue from product sales and may never be profitable.

We are a clinical-stage biotechnology company with a limited operating history. We will need to raise substantial additional capital to continue to fund our operations in the future. We have based our estimates on assumptions that may prove to be wrong, and could exhaust our available financial resources sooner than we currently anticipate. We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, organizing and staffing our company, and providing general and administrative support for our operations.

Developing our product candidates requires a substantial amount of capital. We expect our research and development expenses to continue to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical studies and clinical trials. We will need to raise additional capital to fund our operations, and such funding may not be available to us on acceptable terms, or at all, and such funding may become even more difficult to obtain due to rising interest rates and a downturn in the U.S. capital markets and the biotechnology sector in general. Competition for additional capital among biotechnology companies may be particularly intense during economic downturns. We may be unable to raise capital through public offerings of our ordinary shares and may need to turn to alternative financing arrangements. Such arrangements, if we pursue them, could involve the issuance of one or more types of securities, including ordinary shares, preferred shares, convertible debt, warrants to acquire ordinary shares, or other securities. These securities could be issued at or below the then prevailing market price for our ordinary shares. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of shareholders until the principal, accrued and unpaid interest, and any premium or make-whole has been paid. Interest on any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and reduce our net income (or increase our net loss), and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our ordinary shares, the market price of our ordinary shares could be materially and adversely affected.

We do not currently have any products approved for sale and do not generate any revenue from product sales. Accordingly, we expect to rely primarily on equity and/or debt financings to fund our continued operations. Our ability to raise additional funds will depend, in part, on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic, and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back, or discontinue the development or commercialization of our product candidates;

- seek strategic partnerships, or amend existing partnerships, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of the company to a third party at a price that may result in a loss on investment for our shareholders; or
- file for bankruptcy or cease operations altogether (and face any related legal proceedings).

Any of these events could have a material adverse effect on our business, operating results, and prospects.

Even if successful in raising new capital, we could be limited in the amount of capital we raise due to investor demand restrictions placed on the amount of capital we raise or other reasons.

Additionally, any capital raising efforts are subject to significant risks and contingencies, as described in more detail under the risk factor titled "*Raising additional capital may cause additional dilution to our shareholders, restrict our operations, or require us to relinquish rights.*"

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory approvals for our product candidates for which we complete clinical trials;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- qualifying for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we obtain regulatory approval;
- marketing, launching, and commercializing product candidates for which we obtain regulatory approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products and technological and market developments;
- implementing internal systems and infrastructure, as needed;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter in the future;
- obtaining coverage and adequate reimbursement from third-party payors and maintaining pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by regulatory authorities to perform clinical and other studies in addition to those that we anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable

and may need to obtain additional funding to continue operations. We will also have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturers in order to continue development and potential commercialization of our product candidates. For instance, if the costs of manufacturing our drug product are not commercially feasible, we will need to develop or procure our drug product in a commercially feasible manner in order to successfully commercialize a future approved product, if any. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We are a clinical-stage biotechnology company with a limited operating history on which to assess our business; we have not completed any clinical trials, have no products approved for commercial sale, have historically incurred losses, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Since September 19, 2024 (inception), we have incurred significant operating losses. For the nine months ended September 30, 2026, we reported a net loss of $85.8 million and had an accumulated deficit of $257.7 million. We will need to raise substantial additional capital to continue to fund our operations in the future. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. If we are unable to acquire additional capital or resources, we will be required to modify our operational plans to complete future milestones and we may be required to delay, limit, reduce, or eliminate development or future commercialization efforts of product candidates and/or programs. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings or entering into strategic collaborations.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, organizing and staffing our company, and providing general and administrative support for our operations. To date, we have funded our operations primarily from the sale and issuance of convertible preferred and common equity securities and unsecured convertible notes. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates enter more advanced clinical trials. It may be several years, if ever, before we complete pivotal clinical trials and/or have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current programs to determine the potential to advance product candidates to regulatory approval. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, coverage, and adequate reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the preclinical and clinical development of our product candidates;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our product candidates into larger, more expensive clinical trials;
- initiate additional preclinical studies or clinical trials for our product candidates;
- seek regulatory approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;

- make milestone, royalty, or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- are required to pay penalties under our Registration Rights Agreement for failing to timely register or maintain effectiveness of such registration statement for the applicable securities;
- seek to attract and retain skilled personnel;
- experience any delays or encounter issues with the development and potential regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support regulatory approval; and
- incur additional costs associated with operating as a public company.

We have limited experience as a company in initiating and conducting clinical trials, and no experience in completing clinical trials. In part because of this limited experience, we cannot be certain that our ongoing or planned clinical trials will begin or be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we have financed our cash needs and expect to finance future cash needs through a combination of equity offerings, debt financings, and license and development agreements. To the extent that we raise capital through the additional sale of equity securities or through convertible debt securities, the ownership interest of our shareholders will be further diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our ordinary shares. 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.

We have in the past, and we may in the future, raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, and we may be required to relinquish valuable rights to our 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under convertible debt or other securities convertible into equity, the ownership interest of our shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our shareholders. For instance, immediately prior to the consummation of the Merger, certain institutional and accredited investors purchased shares of Pre-Merger Crescent common stock and pre-funded warrants for an aggregate purchase price of $200.0 million (which includes $37.5 million of gross proceeds we previously received from the issuance of the Convertible Notes in October 2024). Additionally, in December 2025, certain investors agreed to purchase ordinary shares of Crescent and pre-funded warrants for an aggregate purchase price of $185.0 million and in July 2026, we sold approximately 9.4 million of our ordinary shares and 525,897 pre-funded warrants exercisable for our ordinary shares in an underwritten public offering for net proceeds of approximately $133.4 million, after deducting underwriting discounts and commissions and other offering expenses. In addition, we are able to sell up to $188.5 million of our ordinary shares through an “at-the-market” equity offering program.

Debt financing, if available, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant

licenses on terms that are not favorable to us. We cannot assure that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

Risks Related to Discovery, Development, and Commercialization

We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.

The development and commercialization of drugs is highly competitive. Product candidates developed by us, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, including Merck, Bristol Myers Squibb, Genentech, AstraZeneca, Summit Therapeutics Inc., BioNTech SE, LaNova Medicines Ltd., and Compass Therapeutics, Inc., as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing regulatory approved products than we do, and are further along in the clinical development and/or commercialization process than we are. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, raising capital, registering patients for clinical trials, establishing and defending rights to intellectual property, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed, are developing, or may in the future develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any potential new treatments, including those currently under clinical development. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing, and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance. Conversely, the lack of commercial success of other competing programs may raise concerns about the financial viability of our programs.

We are substantially dependent on the success of our lead program, CR-001, as well as our ADC programs, CR-002 and CR-003, and our development programs may not be successful.

Our future success is substantially dependent on our ability to timely obtain regulatory approval for, and then successfully commercialize, our lead program, CR-001. We also intend to advance our ADC programs, CR-002 and CR-003. We are investing a majority of our efforts and financial resources into the research and development of these programs. We believe the success of CR-001 is dependent on observing in CR-001 the targeting, binding, cooperativity and pharmacokinetics of ivonescimab, an anti-PD-1/anti-VEGF bispecific antibody that demonstrated significantly improved progression-free survival (“PFS”) to market-leading pembrolizumab in a large third-party Phase 3 clinical trial, while avoiding the mechanistic risks that could perturb the balance of efficacy and safety that define this new class of immunotherapy. To the extent we do not observe the above-noted targeting, binding, cooperativity and pharmacokinetics in CR-001, or are otherwise unsuccessful in our efforts to develop CR-001, it would significantly and adversely affect the clinical and commercial potential of CR-001.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical, and manufacturing activities, product development, regulatory approval in multiple jurisdictions, substantial investment, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approval.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats

to our intellectual property rights, and the manufacturing, marketing, distribution, and sales efforts of any current or future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in obtaining regulatory approval and commercializing our CR-001, CR-002, CR-003 and any future programs, including CR-004, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and our expenses may increase and, as a result, our share price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and clinical trials in solid tumor and other target indications, as well as the receipt of clinical data, and submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our product candidates may be delayed or never achieved and, as a result, our share price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Any drug delivery device that we potentially use to deliver our product candidates may have its own regulatory, development, supply and other risks.

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to develop do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. For example, the FDA's review of a marketing application for our product candidates may include the participation of both the FDA's Center for Biologics Evaluation and Research and the FDA's Center for Devices and Radiological Health. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying biologic component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device which may delay the approval of the combination product.

In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.

Our approach to the discovery and development of our programs, particularly CR-001, leverages clinically validated mechanisms of action and incorporates the targeting, binding, cooperativity and pharmacokinetics of ivonescimab, an anti-PD-1/anti-VEGF bispecific antibody that demonstrated significantly improved PFS to market-leading pembrolizumab in HARMONi-2, a large Phase 3 clinical trial, sponsored by Akeso, for the treatment of naïve, or not previously treated, advanced and metastatic NSCLC. Our programs are purposefully designed to avoid mechanistic risks that could perturb the balance of efficacy and safety that defines this new class of immunotherapy. However, the scientific research that forms the basis of our efforts to develop programs using ivonescimab-like technologies is ongoing and may not result in viable

programs. There are limited clinical data available on product candidates utilizing the same mechanism of action as ivonescimab, especially in solid tumor indications, demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of these technologies and exposure profile of our programs compared to currently approved products is unknown. Additionally, there can be no assurance that our ongoing and planned clinical trials will generate results compared to those observed for ivonescimab, particularly where we conduct trials outside of NSCLC.

We may ultimately discover that reproducing ivonescimab's established pharmacology for its specific targets and indications and any programs resulting therefrom does not possess certain properties required for therapeutic effectiveness. We currently have only preclinical data regarding the ivonescimab-like properties of our programs and the same results may not be seen in humans. In addition, programs using ivonescimab-like technologies may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. This technology and any programs resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective, or harmful ways. Many product candidates that appeared highly promising in preclinical studies or in early-stage clinical trials have failed when advanced into, or further in, clinical development. In addition, the failure of companies that are developing products similar to us or targeting the same indications as we are to demonstrate safety and efficacy of their product candidates may be harmful to our business, financial condition, results of operations, and prospects.

In addition, we may in the future seek to discover and develop programs that are based on novel targets and technologies that are unproven. If our discovery or business development activities fail to identify novel targets or technologies for drug development, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications, or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from our programs prove to be ineffective, unsafe, or commercially unviable, such programs would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety purity, potency, and efficacy of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug application ("IND") or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned preclinical studies or clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with Contract Research Organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards ("IRBs"), or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice ("GCP") requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO"), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current Good Manufacturing Practice ("cGMP") or similar foreign requirements, regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we are doing for CR-001 and may may do for our future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

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 comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union ("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. While the EU Clinical Trials Directive required a separate clinical trial application ("CTA"), to be submitted in each EU member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully 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 development plans.

If we encounter difficulties enrolling patients in our ongoing and future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult for us to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Preliminary, "topline", initial or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline 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 or subsequently made subject to audit and verification procedures. As a result, any preliminary or topline data should be viewed with caution until the final data are available. From time to time, we may also disclose initial or interim data from our preclinical studies and clinical trials. Such data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, disclosure of such data by us could result in volatility in the price of our ordinary shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and us in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. As a result, you or others may have reached different conclusions based on such extensive information in comparison to our publicly disclosed conclusion regarding a particular preclinical study or clinical trial. If the preliminary, topline, or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Use of our product candidates could be associated with adverse side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved product or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone or in combination with other

therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, when used alone or in combination with other approved products or investigational drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. If such significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

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

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

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

We may attempt to obtain accelerated approval of our product candidates. If we are unable to obtain accelerated approval, we may be required to conduct clinical trials beyond those that we contemplate, or the size and duration of our

pivotal clinical trials could be greater than currently planned, which could increase the expense of obtaining, reduce the likelihood of obtaining, and/or delay the timing of obtaining necessary regulatory approvals. Even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, the FDA or comparable foreign regulatory authorities may require that we conduct confirmatory trials to verify clinical benefit. If such confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-approval requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may seek accelerated approval for our product candidates. The FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease.

If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's predicted effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that any such confirmatory study be initiated or substantially underway prior to the submission of an application for accelerated approval. If such post-approval studies fail to confirm the drug's clinical benefits relative to its risks, the FDA may withdraw its approval of the drug on an expedited basis.

If we choose to pursue accelerated approval, there can be no assurance that the FDA will agree that we have identified appropriate surrogate or intermediate endpoints. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type.

Even if we receive accelerated approval of any of our product candidates from the FDA, we will be subject to rigorous post-approval requirements, including submission to the FDA of all promotional materials prior to their dissemination, and will likely be required by FDA to conduct a confirmatory study to verify the predicted clinical benefit. The FDA could withdraw accelerated approval for multiple reasons, including our failure to conduct any required post-approval study with due diligence, or the inability of such study to confirm the predicted clinical benefit. A failure to obtain accelerated approval or any other form of expedited review or approval for a product candidate could result in a longer time period prior to commercializing such product candidate, if ever, increase the cost of development of such product candidate, and harm our competitive position in the marketplace.

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

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs. We have in the past and may again in the future utilize Paragon Therapeutics, Inc. ("Paragon") to conduct certain research activities (primarily preclinical studies) pursuant to discovery and option agreements into which we may enter.

For example, we are initially focused on our lead programs, CR-001, CR-002 and CR-003. As a result, we may forgo or delay pursuit of opportunities with other programs such as CR-004 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, historically we have selected product candidates amongst a variety of potential product candidates from Paragon, and the product candidates we have selected, initially CR-001 and CR-002, may fail to be viable commercial products or the product candidates we do not select may have a greater likelihood of success.

Any approved products resulting from our current programs or any future program may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors, and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, they may not gain market acceptance among physicians, healthcare professionals, patients, healthcare payors, or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There are several approved products and product candidates in later stages of development for the treatment of solid tumors, including pembrolizumab. In addition, Opdivo, a PD-1 inhibitor, and Yervoy®, a CTLA-4 inhibitor, in combination are approved by the FDA for treating various cancers, including metastatic melanoma, advanced renal cell carcinoma, and certain types of colorectal cancer. CR-001 utilizes a proprietary anti-PD-1/anti-VEGF bispecific antibody for its proposed method of action, and is designed to recapitulate the targeting, binding, cooperativity and pharmacokinetics of ivonescimab, an anti-PD-1/anti-VEGF bispecific antibody that demonstrated significantly improved PFS to market-leading pembrolizumab in a large third-party Phase 3 clinical trial. Although checkpoint inhibitors are highly effective in some patients, most patients with solid tumors fail to respond to these therapies. Furthermore, patients who do respond do not always achieve durable responses. With respect to CR-002 and CR-003, regarding ADC development, we are aware of other ADC product candidates in clinical development for solid tumor indications, including, but not limited to, PDL1V (Pfizer), HLX-43 (Henlius), sigvotatug vedotin (Pfizer). Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that uses cooperative binding qualities for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. Serious adverse events, including fatal pulmonary hemorrhage, observed in anti-VEGF inhibitors, such as bevacizumab, may adversely affect our ability to gain market acceptance. Market acceptance of our product candidates may be negatively impacted by potential poor performance of our competitors, including the occurrence of serious adverse events in such competitors' clinical trials or failure by such competitors to obtain and maintain regulatory approval for their product candidates.

Sales of medical products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies, or private insurers will determine that our product is safe, therapeutically effective, cost effective, or less burdensome as compared with competing treatments. If any of our product candidates are approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. Market acceptance of our product candidates will depend on many factors, including factors that are not within our control.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing product candidates for the same indication, solid tumors, and may in the future develop our programs for other oncology indications. Each such program targets a different mechanism of action. However, developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple product candidates are approved for the same indication, they may compete for market share, which could limit our future revenue.

We conduct clinical trials for our CR-001 program, and expect to conduct clinical trials for future programs, at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are currently conducting clinical trials for CR-001 at sites outside of the United States, and expect to conduct one or more of our future clinical trials for CR-002, CR-003, and any other future programs outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-

conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials 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 relevant jurisdiction. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive, and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead program, CR-001, and other programs, including CR-002 and CR-003, as well as planned programs such as CR-004, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication, or with respect to our product candidates regulated as biologics, that such candidates are safe, pure, and potent for their intended uses. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining regulatory approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other data.

Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe, pure, potent, or effective for its proposed indication(s);
- the results of clinical trials may not meet the level of statistical persuasiveness required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by patients in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling, and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations, or revise existing regulations, or take other actions, which may impact our clinical development plans or prevent or delay approval of our programs under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance.

Additionally, we expect that certain product candidates may be regulated as a combination product that consists of both a biologic and a medical device. Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of regulatory requirements and potentially by different FDA centers. As a result, such product candidates may raise regulatory, policy and review management challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post approval modifications. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve any of our 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 trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired.

We may not be able to meet requirements for the chemistry, manufacturing, and control of our programs.

In order to receive approval of its products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control, and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing, and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing, and control requirements, we may not be successful in getting our products approved.

In addition, as product candidates progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, stability, purity, yield and manufacturing batch size, minimize costs

and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives and/or may lead to delays and additional costs. Additionally, any changes we may make to our product candidates may cause such candidates to perform differently than in prior clinical trials, or could negatively affect our ability to utilize or interpret our existing data. Such changes could delay initiation or completion of clinical trials, lead to negative trial results, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay potential regulatory approval and jeopardize our ability to commercialize our product candidates or generate revenue.

Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product.

We believe that any of our product candidates approved as biologics 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 our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of uncertain marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive 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 our product candidates.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training, and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, or if we are unable to comply with applicable regulatory requirements, a regulatory authority may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, refusals to approve pending applications, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements, and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and

generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, 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 published a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. The proposed revisions remain subject to final approval by the European Parliament, which is currently expected by the end of 2026. The proposed revisions (which would affect, among other things, the duration of regulatory data protection and market protection, including for orphan medicinal products, and revise the eligibility for expedited pathways etc.) are not expected to become applicable before 2028 but may have a significant impact on the pharmaceutical industry and our business over the long term.

Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set.

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

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through the 2032 fiscal year, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. Among other things, the IRA (i) directs the Department of Health and Human Services, or HHS to

negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare; (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; (iii) reduces the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions took effect progressively starting in fiscal year 2023. The Centers for Medicare & Medicaid Services, or CMS, published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next 15 drugs that will be subject to negotiation. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's drug price negotiation program provisions. The outcome of this litigation as well as the effects of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

More recently, the One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The current Presidential administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how such policies will be implemented, the proposed policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. As part of this strategy, President Trump has proposed imposing significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. Subsequently, in April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, which took effect in phases for specified categories of companies beginning July 31, 2026, and applied to all covered importers as of September 29, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. In addition, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. The final Globe regulation was published in September 2026 and implements a mandatory payment model under which manufacturers of eligible drugs will be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. A voluntary payment model, referred to as Generous, seeks to impose most favored nation pricing in Medicaid, and multiple manufacturers have announced their participation. While the impact of the final Globe and proposed Guard regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

At the state level, state governments have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing laws and other healthcare reform measures both at the federal and state level that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or EU 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 medicines, 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 medicines 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 our 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 Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It 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 highest 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 technology, and making decisions on pricing and reimbursement.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. 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 our current or 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 obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. 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 federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics 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 and 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 nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require pharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to it, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against it, our business may be impaired.

The successful commercialization of any of our current or future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as any of our current or future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments or other cost-sharing that patients find unacceptably high.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and offer to reimburse patients only for a less expensive competitor product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage or implement prior authorization or step therapy programs for new or innovative devices or drug therapies before they will reimburse patients who use such therapies, which may be time-consuming or costly for patients and lead to a reduction in revenue. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for any of our current or future product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of any of our current or future product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and regulatory changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See “Risks

Related to Government Regulation—*Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set*" for additional related information.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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

In some countries, particularly member states of the EU ("EU member states"), the pricing of prescription medicinal product is subject to governmental control. EU member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a medicinal product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. This Health Technology Assessment ("HTA process"), which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations, or prospects could be materially and adversely affected.

The UK controls the cost of branded prescription pharmaceuticals through a voluntary scheme and a statutory scheme, the latter of which is applicable to companies that do not opt-in to the former. These schemes require participating manufacturers or suppliers to make payments calculated as a percentage of net sales income from certain branded medicines, and the applicable payment percentages may be significant and may change over time. The current voluntary scheme and its headline payment rate are applicable until the end of 2028, when successor scheme will become applicable – the details of which are not yet known. If the UK were to significantly alter its regulations or agreements affecting the reimbursement or pricing of prescription pharmaceuticals, we could face significant new costs.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages, changes or reductions in agency personnel, or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized

in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency 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.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in previous years, including in 2018, 2019 and 2025, the U.S. government shut down and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial personnel and leadership changes, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities, or otherwise affect our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

If a prolonged government shutdown occurs, or if funding shortages, personnel changes, policy changes or similar factors prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other routine activities, such events could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

We do not currently solely own any issued patents or pending patent applications. Therefore, our ability to obtain and protect our patent rights, and protect other proprietary rights, is uncertain, exposing us to the possible loss of competitive advantage.

Our success depends, and will continue to depend, in large part on our ability to obtain and maintain patent protection for our platform technologies, programs, and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. Our ability to protect our technologies from unauthorized making, using, selling, offering to sell, or importing by third parties may depend on the extent to which we have rights under valid and enforceable patents that cover these activities. We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection, confidentiality agreements, and licensing and collaboration arrangements to protect and expand the intellectual property related to our programs and technologies. While we do not currently solely own any patents or patent applications, we in-license certain patent rights from Paragon pursuant to the CR-001 License Agreement and the CR-002 License Agreement relating to certain of our product candidates, and patent rights from Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. ("Kelun") pursuant to that certain License and Collaboration Agreement, dated December 2, 2025, by and between us and Kelun (the "SKB105 License Agreement") relating to CR-003 outside of mainland China, Hong Kong, Macau and Taiwan. Paragon has filed and we, alone and/or jointly with Paragon, have filed or intend to file provisional patent applications directed to antibodies that target PD-1 and VEGF, including, for example, applications covering composition of matter, dosing, pharmaceutical formulations, and methods of using such antibodies, including, but not limited to, CR-001. In addition, Paragon has filed and we, alone and/or jointly with Paragon, intend to file provisional patent applications directed to ADCs, including, for example, applications covering composition of matter, dosing, pharmaceutical formulations, and methods of using such antibodies, including, but not limited to, CR-002. Kelun has filed, and we and Kelun, alone and/or jointly, intend to file patent applications directed to ADCs, including, for example, applications covering composition of matter, dosing, pharmaceutical formulations, and methods of using such antibodies, including, but not limited to, CR-003. However, we or our licensors may not be able to protect our owned or in-licensed intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets, and other intellectual property. Filing, prosecuting, and defending patents on programs worldwide would be expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do not have patent protection and/or pending patent applications.

Our intellectual property portfolio is at an early stage. We do not currently solely own any issued patents or pending patent applications. Our in-licensed or future solely owned patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our programs or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products, or programs. Even if these patents are granted, they may be difficult to enforce. If we do not obtain patent coverage for the work we are conducting, or if we obtain such rights but they are invalidated or rendered unenforceable, we may be unable to exclude competitors from pursuing and marketing the same or similar product candidates. Other risks we face if we are not able to obtain and maintain patent coverage for our product candidates are the reduction in valuation of our product candidates, and ultimately of us as a company, by potential investors, and our inability to assert claims for infringement against third parties or counterclaim against such third parties or negotiate more advantageous settlement parameters. Further, any issued patents that we may license or own covering our programs could be narrowed or found invalid or unenforceable if challenged in court and/or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office ("USPTO"). Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection may be reduced. Thus, the patents that we may own and/or license may not afford us any meaningful competitive advantage.

In addition to seeking patents for some of our technology and programs, we may also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities, or third-party consultants and vendors that we engage to perform research, clinical trials, or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely, and will continue to rely, in part on confidentiality agreements and, if applicable, material transfer agreements, consulting agreements, or other similar agreements prior to beginning research and/or disclosing proprietary information with parties, such as collaborators, employees, consultants, outside scientific collaborators, and sponsored researchers and other advisors. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with current or future business partners, licensors, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or state actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Enforcing a claim that a party disclosed or misappropriated our trade secrets, or securing title to an employee- or consultant-developed invention if a dispute arises, is challenging and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. 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, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, competitors may discover our trade secrets, 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 would impair our competitive position and have an adverse impact on our business.

Lastly, if our trademarks and trade names are not registered or 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 we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed.

Because our development programs currently rely, and will continue to rely, on intellectual property rights in-licensed from Paragon and Kelun under each of the CR-001 License Agreement, CR-002 License Agreement (together with the

CR-001 License Agreement, the "Paragon License Agreements") and SKB105 License Agreement, respectively, and may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may in the future be unable to acquire or in-license compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our programs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on commercially reasonable terms or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we do obtain, our ability to commercialize any of our targeted therapeutics, if approved, would likely be delayed, or we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Certain of our current or future in-licensed patent families were or may be drafted, filed, and prosecuted by our current or future licensors, including Paragon and Kelun, and even where we now control the right to prosecution of certain in-licensed patent families, we are and may in the future be required to solicit input and consider comments from Paragon, Kelun or other future licensors. Additionally, while we have obtained or intend to obtain the right to control the prosecution, defense, maintenance, and enforcement of certain patents relating to our programs, there may be times when the filing and prosecution activities for patents and patent applications relating to our programs are solely or substantially controlled by our future licensors or collaboration partners. If we, Paragon, Kelun or any of our future licensors or collaboration partners fail to prosecute, maintain, and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected, and we may not be able to prevent competitors from making, using, selling, and importing competing products. In addition, even if patents are issued from patent applications prosecuted by our licensors, our licensors may determine not to pursue litigation against third parties that are infringing these patents or may pursue such litigation less aggressively than we would. In addition, even where we are granted the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our current or future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, including with respect to the use, field, or territory of the licensed intellectual property, 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 redesign our technology, programs, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, programs, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors or partners; and the priority of invention of patented technology. If we or our current or future licensors breach the terms of our license agreements, such breach may have a material adverse effect on our business and the commercialization efforts for our programs.

Our current collaboration with Kelun and any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Our current or future collaborations, including our current collaboration with Kelun, may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may 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 or business risk;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products or products;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without unintentionally infringing on or violating third-party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or more of our product candidates, or our actions relating thereto, infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be enjoined and potentially forced to abandon any affected product candidate and/or seek a license from the patent holder, which may include ongoing royalty obligations. In addition, any intellectual property claims (e.g., patent infringement or trade secret misappropriation) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that our current or future owned or in-licensed patent applications and patents, if filed and issued, will not be challenged by others, whether in the course of litigation or in agencies like the USPTO or foreign administrative bodies. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds.

Competitors may infringe or otherwise violate our current or future patents, trademarks, copyrights, or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including

claims alleging that we infringe their patents or other intellectual property rights and/or that our patents are invalid and/or unenforceable. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our future patents, if filed and issued, through procedures created to challenge the validity of a patent before administrative bodies in the United States such as the USPTO or abroad. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, *e.g.*, opposition proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in 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.

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

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

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to our employees, we engage the service of consultants to assist us in the development of our programs. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how, or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our programs, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

We currently in-license granted patents related to our programs. Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith Act could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications, if any, and the

maintenance, enforcement, or defense of our owned and in-licensed issued patents, if any. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, if any, and the enforcement or defense of our issued patents, if any, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Additionally, the USPTO and patent offices in other jurisdictions have often required that patent applications directed to pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Accordingly, our patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in *Amgen, Inc. v. Sanofi* (Amgen) recently held that Amgen's patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided twenty-six exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in *Amgen* or other recent precedential court decisions. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend, and enforce our patent rights in the future.

Geopolitical instability in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement, or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for EU Member States. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our future owned or in-licensed European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection

in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects, and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms.

Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We or our current or future licensors may decide to opt out from the UPC any future European patent applications that we or our current or future licensors may file and any patents we or such licensors may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that any of our future owned or in-licensed European patents and patent applications will avoid falling under the jurisdiction of the UPC, even if we or our current or future licensors decide to opt out of the UPC.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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.

Periodic maintenance fees, renewal fees, annuities fees, and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain our current or future owned or in-licensed patents and patent applications covering our programs, our competitive position would be adversely affected.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent, the patent's prosecution history, and in some cases certain extrinsic evidence of the meaning of terms in a claim. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our future owned or in-licensed issued patents or our current or future owned or in-licensed pending applications, if filed, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours. Any such patent application may have priority over our current or future owned or in-licensed patent applications or patents, if filed and issued, which could require us to obtain rights to issued patents covering such technologies.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our future owned or in-licensed patents, if filed and issued, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs, or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. While we typically require employees, consultants, and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date or international Patent Cooperation Treaty Filing. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension (“PTE”) of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of an enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication - in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we anticipate prosecuting patents, and we likewise anticipate applying for such extensions.

The granting of a PTE is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue a PTE based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

The technology we currently license from Paragon and Kelun and any future technology we may license from various third parties in the future, may be subject to retained rights.

Our current and future licensors may retain certain rights under the relevant agreements with us, including the right to use or license the licensed technology outside of the scope of our license, use the underlying technology for noncommercial

academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, while we seek to obtain certain restrictions on our current or future licensors' abilities to develop products that could be competitive with ours, these restrictions may not prevent the possible future license or development by our current or future licensors, including Paragon or Kelun, of certain technology that could lead to product candidates competitive with ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We may be unable to protect the confidentiality of our trade secrets and other proprietary information.

Our success depends, in part, on our ability to maintain the confidentiality of our proprietary know-how, trade secrets, and other confidential information, including product candidate sequence information, manufacturing processes, formulation technologies, dosing regimens, analytical techniques, and other technical information that provides us with a competitive advantage. We rely, and will continue to rely, on confidentiality agreements and other contractual protections with employees, consultants, collaborators, contract manufacturers, and other third parties to protect our trade secrets and proprietary information. However, these agreements may not effectively prevent unauthorized disclosure or use of our confidential information and may not provide an adequate remedy in the event of such disclosure or use. Despite our efforts to protect our trade secrets and proprietary information, unauthorized parties may attempt to obtain, copy, or use our proprietary technologies and information through various means, including cyber incidents, reverse engineering, physical breaches of our facilities, or misappropriation by current or former employees, consultants, advisors, contractors, or other third parties with whom we share our proprietary information. The risk of unauthorized disclosure or misappropriation is heightened given the number of third parties with whom we must share confidential information in connection with clinical trials, regulatory submissions, manufacturing arrangements, and strategic collaborations. For example, our contract manufacturing organizations and clinical trial sites must have access to certain proprietary manufacturing processes, formulation information, and clinical data to perform their contracted services. Any disclosure, intentional or unintentional, by our employees, consultants, or collaborators, or any misappropriation by third parties, of our trade secret or proprietary information could enable competitors to duplicate or surpass our products, potentially harming our competitive position. Trade secret protection may also be inadequate if we are unable to demonstrate that information qualifies for protection under the Defend Trade Secrets Act of 2016 or state or local laws, if we fail to take reasonable measures to maintain its secrecy. If we are unable to maintain the confidentiality of our proprietary technology, know-how, and other confidential information, our ability to obtain patent protection or to protect our proprietary information may be jeopardized, competitors may be able to use our technologies to develop competing products, and our business, financial condition, and results of operations could be materially and adversely affected.

BPCIA litigation is complex, costly, and unpredictable, and unfavorable outcomes could result in the invalidity or unenforceability of our patents.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) established an abbreviated regulatory pathway for biosimilar product candidates, along with procedures for patent disputes between reference product sponsors and biosimilar applicants. Under the BPCIA, biosimilar applicants may submit an abbreviated biologics license application seeking approval to market biosimilar versions of our biological products. The BPCIA provides for an information exchange process known as the "patent dance" designed to identify relevant patents and facilitate early resolution of patent disputes; however, participation in the "patent dance" is not required by biosimilar applicants. The BPCIA patent litigation framework is relatively new, and judicial precedent interpreting its provisions continues to evolve, creating uncertainty. As soon as four (4) years after approval of a product by the FDA, we may be subjected to BPCIA litigation brought by biosimilar applicants and forced to defend our intellectual property rights covering that product, and such litigation is likely to be expensive, time-consuming and complex. Competitors may challenge our patents by filing abbreviated biologics license applications and declining to fully participate in the patent dance, forcing us to file patent infringement lawsuits on short timelines or potentially forfeiting our ability to assert certain patents. The BPCIA framework allows biosimilar applicants to control certain aspects of the litigation process, including the timing of their notice of commercial marketing, which triggers additional patent enforcement opportunities but may result in sequential waves of litigation extending over several years. Patent litigation under the BPCIA may involve patents covering various aspects of our products, including composition of matter, formulations, manufacturing processes, and methods of use, and we may face difficulty in demonstrating infringement of certain types of patents. If we are unsuccessful in such litigation or if courts invalidate, hold unenforceable, or narrowly construe our patents, biosimilar competitors could enter the market, which could significantly harm our business. Even if we are successful in patent litigation, the length and expense of such proceedings could divert management attention and financial resources from our business operations. We may face biosimilar competition even if our patents are held to be valid and enforceable and have additional remaining terms, particularly where competitors

successfully design around our patents or demonstrate that their products do not infringe. Our inability to adequately protect patents covering our products from biosimilar competition could materially and adversely affect our business.

Risks Related to Our Reliance on Third Parties

We currently rely on licensing arrangements with Paragon and Kelun under the Paragon License Agreements, the Kelun CR-001 License Agreement, and the SKB105 License Agreement and may in the future rely on other intellectual property licensed from third parties. If we are unable to maintain our current collaborations or licensing arrangements, or if our collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We rely on our current and future licensing arrangements with Paragon and Kelun under the Paragon License Agreements, the Kelun CR-001 License Agreement, and the SKB105 License Agreement for intellectual property rights underlying our current product candidates, and may in the future rely on licensing arrangements with other third parties for rights to a substantial portion of our discovery capabilities and product candidates, including for CR-001 and CR-002.

Our current or future collaborations or licensing arrangements may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our current or future collaborators or licensors experiences delays in performance of, or fails to perform, its obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement, or terminates their agreement with us, our programs could be adversely affected. If we fail to comply with any of the obligations under our current or future collaborations or license agreements, including payment terms and diligence terms, such as requirements to use commercially reasonable efforts to develop and commercialize products covered by the licensed intellectual property rights in our respective territory, our current or future collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market, or sell the products covered by our agreements or may face other penalties under our agreements. Our current or future collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, our current or future collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or provide development or commercialization capabilities that complement ours. We may not realize the benefits of such collaborations or licensing arrangements. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

We may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document, and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs, and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over

the conduct, timing, and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our programs in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications we may submit. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations or similar foreign requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may be involved in mergers, acquisitions, or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our product candidates. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any application we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

In addition, our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize our product candidates.

We rely on third parties who operate in China, which may expose us to additional risks.

In addition, we currently rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited ("WuXi") for CR-001 and CR-002 formulation and manufacturing of our stage 1 clinical trial materials, and will likely continue to rely on foreign CROs and CMOs in the future. Kelun is also based in China. On December 18, 2025, President Trump signed into law the National Defense Authorization Act of 2026 ("NDAA"), which includes § 851 often referred to as "the BIOSECURE Act". Under the BIOSECURE Act, U.S. government agencies cannot (1) buy or obtain biotechnology equipment or services provided by a "biotechnology company of concern" ("BCC"); (2) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC; or (3) expend loan or grant funds for biotechnology equipment or services provided by a BCC, whether directly or through a loan or grant recipient. The BIOSECURE Act does not bar a U.S. company from all federal contracts or grants simply because it does business with a BCC. The restriction applies only when a federal contract or grant would procure covered biotechnology equipment or services—directly or indirectly—from a designated company. While WuXi is not currently listed as a BCC, earlier BIOSECURE drafts explicitly named it as a BCC. Additionally, on December 18, 2025, the chairmen of multiple Senate

and House committees, including the House Select Committee on China, sent a letter to the Department of Defense recommending that WuXi be added to the Department of Defense's 1260H list, which would make WuXi a BCC.

However, there are certain safe harbors, waivers, and exceptions to the BIOSECURE Act. The BIOSECURE Act provides a five-year safe harbor for existing contracts with companies later designated as BCCs. The five-year window begins when the Federal Acquisition Regulations ("FAR") are updated to implement the Act's requirements, allowing entities five years to fulfill current contracts, transition to alternative suppliers, and wind down business with BCCs. Further, "biotechnology equipment or services" excludes items previously, but no longer, produced by BCCs. Therefore, an entity may retain and continue to use equipment or technology produced by a BCC prior to the BIOSECURE Act's enactment. Additionally, the Act allows drug manufacturers to remain eligible for the Medicare and Medicaid Drug Part B Rebate Programs if the Department of Veteran Affairs determines that the BIOSECURE Act restrictions are the only reason the drug manufacturer cannot enter the VA master agreement required by the Veterans Health Care Act of 1992 (38 U.S.C. § 8126). Finally, the head of an executive agency may waive the Act's restrictions for up to 365 days, with approval of the Director of the OMB. This waiver can be renewed once for an additional 180 days.

Foreign CMOs may be subject to U.S. legislation, including the BIOSECURE Act, trade restrictions, and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in April 2025, the United States government imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or impose other restrictions on companies' ability to work with Chinese biotech companies. Certain of these tariffs have gone into effect. In February 2026, the United States Supreme Court ruled that the use of the International Emergency Economic Powers Act ("IEEPA") to impose tariffs was not authorized by Congress, invalidating a significant portion of tariffs that had been in effect since April 2025. While the ruling struck down the IEEPA-based tariffs, it does not prevent the administration from imposing tariffs using other legal authorities, and the administration has indicated its intention to pursue alternative statutory mechanisms to reinstate or impose new tariffs. In July 2026, the Trump administration imposed tariffs on goods from more than 80 countries under Section 301 of the Trade Act of 1974, which enables the government to impose tariffs in response to unfair trade practices. These tariffs are the subject of pending litigation, the outcome of which remains uncertain. There remains substantial uncertainty regarding future tariff rates and the countries and products to which such tariffs would apply. To the extent tariffs are applicable to the material we import from China and other countries, our financial condition could be adversely affected.

Further, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations, and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. Furthermore, if any of our China-based collaborators or vendors—including WuXi—are designated a BCC under the BIOSECURE Act, our operations and financial condition could be adversely affected by delays or higher costs stemming from U.S. federal restrictions on contracts, grants, and loans involving BCCs, as well as other applicable foreign regulatory requirements. In addition, while we have established relationships with CROs and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into our development programs.

We currently rely and expect to rely in the future on the use of manufacturing sites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical or commercial manufacturing and processing facility and must currently rely on CMOs to manufacture our product candidates. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have a sole source relationship for our supply of the CR-001 and CR-002 programs, and expect to have a sole source relationship for the supply of the CR-003 program. If there should be any disruption in such supply arrangements, including any adverse events affecting our sole supplier, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners

for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs, delays, and materially adversely affect our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, 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.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition, and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates

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

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs, and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are a clinical stage biotechnology company with a limited operating history, and, as of September 30, 2026, we had 80 full-time employees. We have been and will continue to be highly dependent on the research and development, clinical and business development expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Any of our management team members may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Attracting and retaining qualified personnel will also be critical to our success, including with respect to any strategic transaction that we may pursue. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, facilitate regulatory approval of, and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and nonclinical and clinical development and commercialization strategy. Our consultants and advisors may

be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting, and legal requirements and reduced protection of intellectual property rights in some foreign countries.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers, and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other comparable foreign regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements or similar foreign requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iv) laws that require the true, complete and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our or our collaborators' 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

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

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information).

We may be unable to detect, investigate, remediate or recover from future attacks or incidents, or to avoid a material adverse impact to our information technology systems, confidential information or business. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third-party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to attack, breakdown or other damage or service interruptions, misconfigurations, "bugs" or other vulnerabilities, malicious code, system malfunction, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, other social engineering / phishing schemes, denial or degradation of service attacks and sophisticated nation-state and nation-state-supported actors as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. Furthermore, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. Advances in artificial intelligence, including models capable of rapidly identifying and exploiting software vulnerabilities, may further increase the speed and effectiveness of cyberattacks. As a result, vulnerabilities or flaws in our products, systems or those of third parties upon which we rely may be discovered more quickly, reducing the time available for detection and remediation and increasing the likelihood or severity of security incidents.

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, including the ongoing conflict in Iran, we, and the third parties upon which we rely, 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. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and 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.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Certain members of our workforce are remote, which may create additional risks for our information technology systems and data because our employees who work remotely utilize network connections, computers, and devices working at home, while in transit and in public locations. Additionally, 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that our measures and those of third parties will be effective in protecting our systems, networks and internal information. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process internal information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to it, 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 our third-party partners' supply chains have not been compromised.

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines, and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

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, sensitive third-party data, business plans, transactions and financial information (collectively, sensitive 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.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification 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, the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data

privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to 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 may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018) and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data.

For example, under GDPR, companies may 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.

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

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (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 similarly stringent interpretations of their 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 EU's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for 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 activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in or a contractor of, a covered person or country of concern, as applicable) that 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 engage in certain transactions or agreements with certain third parties in the future.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

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 consumers' 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 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; or orders to destroy or not use personal data.

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; 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, and regulations. These current or future laws and regulations may impair our research, development, or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which may have retroactive application) could adversely affect our shareholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict

whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States enacted the Inflation Reduction Act of 2022 ("IRA"), which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. On July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes provisions that allow for the immediate expensing of domestic U.S. research and development expenses, a general requirement to reduce the deduction for research and development expense by any research credit taken, and other changes to the U.S. taxation of profits derived from foreign operations. The impact of this law on our tax position will depend on how the provision is implemented and interpreted by the Internal Revenue Service and other regulatory authorities. In addition, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. Such changes, among others, may adversely affect our effective tax rate, results of operation, and general business condition.

We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Risks Related to Owning Our Ordinary Shares

Preferred directors elected by the holders of our Series A Preferred Shares have the ability to control or significantly influence all matters submitted to our board of directors for approval.

Pursuant to our Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Shares (the "Series A Certificate of Designation"), at all times when at least 30% of the originally issued Series A Preferred Shares remains issued and outstanding: (i) the holders of our Series A Preferred Shares, exclusively and voting together as a separate class on an as-converted to ordinary shares basis, are entitled to elect two preferred directors (the "Preferred Directors"); and (ii) the holders of our ordinary shares and of any other class or series of voting shares (including our Series A Preferred Shares), exclusively and voting together as a single class on an as-converted to ordinary shares basis, are entitled to elect the balance of the total number of directors of our board. Each Preferred Director is entitled to three votes on each matter presented to our board of directors.

Following the completion of the Merger, Peter Harwin and Jonathan Violin were elected as the two Preferred Directors by the holders of our Series A Preferred Shares. These two directors, in the aggregate, have six votes on each matter presented to the board of directors, representing 60% of the total votes of the board. As a result, these two Preferred Directors are able to control or significantly influence all matters submitted to our board of directors for approval, including business plans and policies and the appointment and removal of our officers. The holders of our Series A Preferred Shares thereby have influence with respect to the composition of our board of directors and, to the extent they influence the actions of the Preferred Directors, if at all, actions of our board of directors. An affiliate of Fairmount is the

sole holder of our Series A Preferred Shares. Mr. Harwin is a Managing Member at Fairmount, and Dr. Violin was previously a Venture Partner at Fairmount.

The decision to enter into or amend any option agreement or license agreement with Paragon is subject to the approval of our board of directors. As noted above, our board of directors includes two Preferred Directors that are affiliated with and elected by Fairmount. As a result, Fairmount may exert influence on the decisions of our board of directors and management, including as it relates to the Company's agreements with Paragon, which interests may differ from the interests of our shareholders given Fairmount's interest in both us and Paragon, and indirect interest in Parascent. All directors of our board of directors owe fiduciary duties pursuant to Cayman Islands law, and are expected to comply with their respective fiduciary duties under Cayman Islands law relevant to related party transactions. In addition, we have adopted a related party transaction approval policy pursuant to which the Audit Committee of our board of directors is responsible for the review, consideration, and approval or ratification of related party transactions.

We are governed by Cayman Islands law, and certain provisions of our Articles of Association have anti-takeover implications.

Our organizational documents are governed by Cayman Islands law, and certain provisions in our Articles of Association may discourage, delay, or prevent a merger, acquisition, or other change in control of the company that shareholders may consider favorable, including transactions in which our ordinary shareholders might otherwise receive a premium price for their ordinary shares. These provisions could also limit the price that investors might be willing to pay in the future for our ordinary shares, thereby depressing the market price of our ordinary shares. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by any shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that not all members of our board of directors are elected at one time;
- allow the authorized number of directors to be changed only by resolution of our board of directors, subject to the terms of the Series A Certificate of Designation;
- limit the manner in which shareholders can remove directors from our board of directors;
- provide for advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at shareholder meetings;
- limit who may call a general meeting of shareholders;
- authorize the board of directors to issue preferred shares without shareholder approval, which could be used to institute a "poison pill" that would work to dilute the share ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require a special resolution passed by the affirmative vote of not less than two-thirds of the votes cast at a general meeting to amend provisions of the Articles of Association.

In addition, the Certificate of Designation relating to our Series A Preferred Shares may delay or prevent a change in control. At any time while at least 30% of the originally issued Series A Preferred Shares remain issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Series A Certificate of Designation) or any merger or consolidation with or into another entity or any share sale to, or other business combination in which our shareholders immediately before such transaction do not hold at least a majority of the share capital immediately after such transaction, without the affirmative vote of the Preferred Directors, acting together, or a simple majority of the then issued and outstanding Series A Preferred Shares. This provision of the Series A Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions, even potential change of control transactions that could offer a premium over market value to the ordinary shareholders, as it would require the separate consent of the Preferred Directors, acting together, or a simple majority of the issued and outstanding Series A Preferred Shares.

Our Articles of Association designate the courts of the Cayman Islands as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit your ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our Articles of Association provide that, unless we consent in writing to the selection of an alternative forum, the courts of the Cayman Islands shall have exclusive jurisdiction over any claim or dispute arising out of or in connection with our Articles of Association or otherwise related in any way to each shareholder's shareholding in us, including, but not limited to: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of any fiduciary or other duty owed by any of our current or former directors, officers or other employees to us or our shareholders; (iii) any action asserting a claim arising pursuant to any provision of the Companies Act or our Articles of Association; or (iv) any action asserting a claim against us governed by the internal affairs doctrine (as such concept is recognized under the laws of the United States of America) and that each shareholder irrevocably submits to the exclusive jurisdiction of the courts of the Cayman Islands over all such claims or disputes. The forum selection provision in our Articles of Association does not apply to actions or suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, or any claim for which the federal district courts of the United States of America are, as a matter of the laws of the United States of America, the sole and exclusive forum for determination of such a claim.

Our Articles of Association also provide that, without prejudice to any other rights or remedies that we may have, each of our shareholders acknowledges that damages alone would not be an adequate remedy for any breach of the selection of the courts of the Cayman Islands as exclusive forum and that accordingly we are entitled, without proof of special damages, to the remedies of injunction, specific performance, or other equitable relief for any threatened or actual breach of the selection of the courts of the Cayman Islands as exclusive forum.

This choice of forum provision may increase a shareholder's cost and limit the shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. Any person or entity purchasing or otherwise acquiring any of our shares or other securities, whether by transfer, sale, operation of law, or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' memorandum and articles of association or other charter documents has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable, and if a court were to find this provision in our Articles of Association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could have an adverse effect on our business and financial performance.

Future sales of shares by existing shareholders, including any shares issuable upon exercise of any pre-funded warrants, could cause our share price to decline.

If our shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares, including shares issuable upon exercise of our pre-funded warrants, in the public market after legal restrictions on resale lapse, the trading price of our ordinary shares could decline. In addition, our ordinary shares that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain, if any, for the foreseeable future.

Our executive officers, directors, and principal shareholders have the ability to control or significantly influence all matters submitted to our shareholders for approval.

Our executive officers, directors, and principal shareholders beneficially own a significant percentage of our outstanding ordinary shares. As a result, if these shareholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these shareholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent our acquisition on terms that other shareholders may desire.

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

The trading market for our ordinary shares will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our ordinary shares, and such lack of research coverage may adversely affect the market price of our ordinary shares. If 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 ordinary shares could decline if one or more equity research analysts downgrade our shares 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 ordinary shares could decrease, which in turn could cause our share price or trading volume to decline.

Our ability to use Net Operating Loss ("NOL") carryforwards and other tax attributes may be limited, including as a result of the Merger.

We incurred losses during our history, and we do not expect to become profitable in the near future and may never achieve profitability. As of December 31, 2025, we had federal and state NOL carryforwards of approximately $46.6 million and $37.5 million, respectively. The federal net operating losses may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. The state net operating losses expire at various dates beginning in 2044. It is uncertain if and to what extent various states will conform to federal law. As of December 31, 2025, we had federal and state research and development tax credit carryforwards of approximately $1.9 million and $0.8 million, respectively, which expire at various dates beginning in 2044. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986 (the "Code"), U.S. 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 shareholders or groups of shareholders who own at least 5% of a company's shares 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. 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.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice, or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we have obtained product liability insurance for our clinical trials, it is possible that any liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured

liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators, and intellectual property rights. Litigation to defend ourself against claims by third parties, or to enforce any rights that we may have against third parties, may continue to be necessary, which could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations, or cash flows.

Our business could be adversely affected by factors outside of our control, including, but not limited to, economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

Broad market and industry factors may negatively affect our operations and the market price of our ordinary shares, including, but not limited to, economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, especially in light of ongoing comments and executive orders made by the Trump Administration, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, fluctuating interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations, and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers. In 2025, the United States announced reciprocal tariffs on a variety of countries and products. In February 2026, the United States Supreme Court invalidated a significant portion of tariffs that had been in effect since April 2025 based on the International Emergency Economic Powers Act (IEEPA). The ruling has created substantial uncertainty regarding the tariff landscape, including the method and timing of any refunds to previously collected tariffs and any imposition of new or similar tariffs under alternative statutory mechanisms, such as those imposed in July 2026 under Section 301 of the Trade Act of 1974. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified, or suspended. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflicts in Iran and elsewhere in the Middle East and between Russia and Ukraine as well as rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. For example, trade policies and geopolitical disputes (including as a result of China-Taiwan relations) and other international conflicts can result in tariffs, sanctions, and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where we source our components or raw materials. In addition, tensions between the United States and China have led to a series of tariffs being imposed by the United States on imports from China mainland, as well as other business restrictions. Tariffs increase the costs of the components and raw materials we source. Countries may also adopt other measures, such as controls on imports or exports of goods, technology, or data, that could adversely impact our operations and supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Moreover, fires and other natural disasters may increase in frequency and severity over time due to climate change. If these earthquakes, fires, other natural disasters and similar unforeseen events beyond our control were to occur, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to initiate or expand our clinical trials, our development plans and business.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Our business could be negatively impacted by sustainability or environmental, social and corporate governance ("ESG") matters or our reporting of such matters.

Certain investors, employees, collaborators, and other stakeholders are focused on sustainability and ESG matters. Moreover, certain governmental authorities have proposed or adopted, and may continue to propose or adopt, certain mandated ESG reporting requirements, which, to the extent adopted, could significantly increase our compliance and reporting costs. In parallel, anti-ESG sentiment has gained momentum in the United States and in other jurisdictions, with the U.S. federal government and several states having enacted or proposed "anti-ESG" policies or legislation. We may be perceived to not be properly balancing these conflicting demands with respect to ESG matters, to be not acting responsibly in connection with these matters or, on the other hand, we may be criticized or perceived as not prioritizing returns to our shareholders by those who criticize a company's focus on ESG matters, either of which could negatively impact us and adversely affect the price of our ordinary shares.

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

(a) None.

(b) None.

(c) During the quarter ended September 30, 2026, no director or officer (as defined in Rule 16a-1(f)) adopted or terminated any Rule 10b5-1 trading arrangement and/or non-Rule 10b5-1 trading arrangement (in each case, as defined in Item 408 of Regulation S-K).

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report are set forth below.

Exhibit Number	Description	Form	Exhibit	Filing Date
2.1†	Agreement and Plan of Merger and Reorganization, dated as of October 28, 2024, by and among GlycoMimetics, Inc., Gemini Merger Sub Corp., Gemini Merger Sub II, LLC, and Crescent Biopharma, Inc.	8-K	2.1	October 29, 2024
2.2†	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated as of February 14, 2025	8-K	10.1	February 14, 2025
2.3†	Amendment No. 2 to Agreement and Plan of Merger and Reorganization, dated as of April 28, 2025, by and among GlycoMimetics, Inc., Gemini Merger Sub Corp., Gemini Merger Sub II, LLC, and Crescent Biopharma, Inc.	8-K	10.1	April 29, 2025
3.1	Memorandum and Articles of Association	8-K	3.4	June 18, 2025
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Shares	8-K	3.6	June 18, 2025

Exhibit Number	Description	Form	Exhibit	Filing Date
4.1	2026 Form of Pre-Funded Warrant	8-K	4.1	July 15, 2026
10.1*#	Amendment No.1 to the Crescent Biopharma, Inc. 2025 Employment Inducement Incentive Award Plan			
10.2	Open Market Sale Agreement℠, dated July 1, 2026, by and between the Company and Jefferies LLC	S-3	1.2	July 1, 2026
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934			
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934			
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934			
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934			
101.INS	Inline XBRL Instance Document.			
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document.			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in exhibit 101).			

* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan or arrangement.

† Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished.

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.

Crescent Biopharma, Inc.

Date: November 12, 2026

By: /s/ Joshua Brumm
Joshua Brumm
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2026

By: /s/ Richard Scalzo
Richard Scalzo
Chief Financial Officer
(Principal Financial Officer)

AMENDMENT NO. 1 TO THE CRESCENT BIOPHARMA, INC. 2025 EMPLOYMENT INDUCEMENT INCENTIVE AWARD PLAN

THIS AMENDMENT NO. 1 TO THE CRESCENT BIOPHARMA, INC. 2025 EMPLOYMENT INDUCEMENT INCENTIVE AWARD PLAN (this "***Amendment***"), is effective as of September 17, 2026, the date the board of directors (the "***Board***") of Crescent Biopharma, Inc., a Cayman Islands exempted company (the "***Company***"), approved the amendment to the Company's 2025 Employment Inducement Incentive Award Plan (the "***Plan***") as set forth herein. Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the Plan.

WHEREAS, the Board may amend the Plan at any time; provided that the Board will obtain shareholder approval of any amendment to the Plan to the extent necessary to comply with applicable laws; and

WHEREAS, the Board desires to amend the Plan as set forth herein.

NOW, THEREFORE, BE IT RESOLVED, that the Plan be and hereby is amended as follows:

1. Section 2(af) of the Plan is hereby amended by deleting the number "1,250,000" and substituting the number "2,000,000" in lieu thereof.

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan.

3. Except as set forth herein, the Plan shall remain in full force and effect.

* * *

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua Brumm, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Crescent Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ Joshua Brumm

Joshua Brumm

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Scalzo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Crescent Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ Richard Scalzo

Richard Scalzo

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua Brumm, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Crescent Biopharma, Inc. (the "Company") for the fiscal quarter ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report") (i), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; (ii), and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joshua Brumm

Joshua Brumm

Chief Executive Officer

(Principal Executive Officer)

November 12, 2026

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Scalzo, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Crescent Biopharma, Inc. (the "Company") for the fiscal quarter ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report") (i), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; (ii), and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Richard Scalzo

Richard Scalzo

Chief Financial Officer

(Principal Financial Officer)

November 12, 2026